Date: 18/11/2026

Direct Healthcare Professional Communication (DHPC)

RISPERDAL CONSTA 50MG Notification to Healthcare Professionals Regarding Packaging and Leaflet Language Deficiency

Dear Healthcare Professionals,

Greetings,

This information is being communicated in agreement with the Saudi Food and Drug Authority (SFDA). With reference to a quality report received regarding the packaging and leaflet language of RISPERDAL CONSTA 50MG (Batch No. QGSK000), manufactured by Janssen, and following review of the affected batch information, we would like to inform you of the following:

Summary:

It has been reported that the outer packaging and internal leaflet of the affected batch include information in a foreign language. To ensure clarity of information for healthcare professionals and safe and effective use of the product, the English Patient Information Leaflet is provided in Annex 1 of this DHPC.

Further information on the Safety concern and recommendations:

- The issue relates to the availability and clarity of product information due to the presence of foreign-language information on the outer packaging and internal leaflet of the affected batch.
- No new safety concern has been identified from this quality notification. The purpose of this communication is to ensure that healthcare professionals have access to the English leaflet and the required product information.
- The English Patient Information Leaflet is attached in Annex 1 and should be used as the reference for product information for the affected batch.

Recommendations:

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet provided in Annex 1 to ensure that all necessary information is clearly communicated for safe and effective use.
- Healthcare institutions are requested to ensure that the English leaflet is available to relevant healthcare professionals handling or administering the affected batch.
- If you require more details regarding this batch, please contact Arabian Oasis for Development and Commercial Investment Company at 0504236833 or via email at Regulatory@aodci.com.sa.
- If you notice any packaging or leaflet with unclear or missing information for any other batch, please report it immediately to the SFDA reporting system: https://ade.sfda.gov.sa/Home/Report.

Attachments:

- Please refer to the Patient Information Leaflet provided in Annex 1.

Call for Reporting

If you experience any adverse events or have concerns related to RISPERDAL CONSTA 50MG, please report via:

- Marketing Authorisation Holder / Manufacturer: Janssen
- Local company contact: Arabian Oasis for Development and Commercial Investment Company, Tel: 0504236833, Email: Regulatory@aodci.com.sa
- National Pharmacovigilance Center (NPC) - Saudi Food & Drug Authority (SFDA): Call Center: 19999, Email: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa.

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.

Sincerely,

Arabian Oasis for Development and Commercial Investment Company

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Risperdal Consta®

Janssen-Cilag AG

Composition active

ingredients

Risperidonum.

Auxiliary supplies

Active ingredient powder (vial): Poly (DL-Lactidum-co-glycolidum).

Lösung zur Suspendierung des Pulvers (Fertigspritze): Carmellosum natricum, Polysorbatum 20, Dinatrii phosphas dihydricus, Acidum citricum, Natrii chloridum, Natrii hydroxidum, Aqua ad iniectabilia q.s. ad solutionem pro 2 ml. Gesamtgehalt Natrium: 9.872 mg.

Dosage form and amount of active ingredient per unit

Powders and solvents for the preparation of a depot suspension for injection in a pre-filled syringe

Risperdal Consta contains risperidone in microspheres (polymer beads) that release the risperidone embedded in it with a delay. Active ingredient powder for the preparation of suspension for injection (vial): Praeparatio sicca of 25 mg, 37.5 mg or 50 mg risperidone. Solvent for suspension of powder (pre-filled syringe): 2 ml.

Indications/Possible applications

Maintenance therapy for psychotic illnesses of schizophrenia after initiation of treatment with non-sustained-release neuroleptics.

Dosage/Application

Usual Dosage Adults

The recommended dosage is 25 mg intramuscularly every other week. Some patients may benefit from higher doses of 37.5 mg or 50 mg. 75 mg showed no additional benefit in clinical trials, and a slightly higher incidence of extrapyramidal adverse events was observed. Doses higher than 50 mg every other week are not recommended.

Caution: After the 1st injection of Risperdal Consta, a clinically effective effect cannot *be expected* immediately, but *only after a latency period of three or even four weeks*. Therefore, sufficient substitution with other antipsychotics must first be ensured during this period, or, if possible, Risperdal must be administered orally. In patients treated with depot antipsychotics, it may be advisable to temporarily switch to oral treatment (if clinically possible) before switching to Risperdal Consta.

A dose increase should not occur more often than every 4 weeks, as the effect can be expected no earlier than 3 weeks after the first injection with the higher dose.

Special dosing instructions

Patients with hepatic and renal impairment

The use of Risperdal Consta in patients with liver and kidney disease has not been studied.

If a patient with liver or kidney disease requires treatment with Risperdal Consta, it is recommended to take an initial dose of 0.5 mg of risperidone orally 2× daily (as a tablet or solution) during the first week. In the 2nd week, the daily dose can be increased to 1 mg 2× daily or 2 mg 1× daily. If an oral dose of at least 2 mg is well tolerated, an injection of 25 mg of Risperdal Consta can be given every 2 weeks.

Elderly patients

The recommended dosage is 25 mg intramuscularly every other week. After the 1st injection of Risperdal Consta, sufficient substitution with other oral antipsychotics must be ensured for the following three weeks (lag phase) (see "Pharmacokinetics").

Older patients with psychotic symptoms in the context of dementia had an increased risk of mortality under treatment with atypical antipsychotics. Risperdal Consta is not approved for the treatment of patients with psychotic symptoms associated with dementia.

Children and adolescents

There is no experience with children and adolescents under the age of 18.

Administration regimen

In patients who have never received risperidone, it is recommended that they test their tolerance with oral risperidone before starting treatment with Risperdal Consta.

Method of administration

Risperdal Consta must be administered every two weeks by deep intramuscular deltoid or gluteal injection. For this purpose, the appropriate safety injection needle must be used. For the deltoid injection, the 1-inch needle (25 mm) should be used, alternating between the two arms during the injections. For gluteal injection, the 2-inch needle (51 mm) should be inserted, whereby the injection should be made alternately into one of the buttock cheeks. Risperdal Consta must not be administered intravenously (see "Warnings and precautions", section "Administration"). For the preparation and administration of the suspension, see "Other instructions": "Instructions for handling".

Contraindications

Known hypersensitivity to risperidonum or other components of the drug.

Demented patients with Parkinson's symptoms in the sense of rigor, bradykinesis and Parkinson's postural disorders.

Dementia patients with the probable diagnosis of Lewybody dementia (in addition to the symptoms of dementia, at least two of the following three symptoms: parkinsonism/visual hallucinations/fluctuation in the course).

Warnings and precautions

In patients who have never been treated with risperidone before, it is recommended to clarify tolerability with the oral form of risperidone before using Risperdal Consta.

Children and adolescents

Since there is no experience so far, Risperdal Consta must not be administered to children and adolescents under 18 years of age.

Elderly patients with

dementia Increased all-cause

mortality

A meta-analysis of 17 controlled trials of atypical antipsychotics, including risperdal, showed increased mortality in elderly antipsychotic-treated dementia patients compared to placebo. In this population, the mortality rate in placebo-controlled studies with oral risperdal was 4.0% in patients treated with risperdal and 3.1% in the placebo group. The mean age of the deceased patients was 86 years (age range 67–100 years).

A specific risk factor profile for the increased mortality with Risperdal is not recognizable. Rather, causes of death were found that are typically observed in the age group >65 years: cardiovascular and cerebrovascular events, tumors, infections (e.g. pneumonia) and diabetes.

Increased mortality with concomitant use of furosemide:

In placebo-controlled studies in elderly patients with dementia, a higher mortality rate was observed with concomitant treatment with risperidone and furosemide (7.3%; mean age 89, age range 75–97 years) than with treatment with risperidone alone (3.1%; mean age 84, age range 70–96) or furosemide (4.1%; mean age 80, age range 67–90 years). The increase in mortality in patients treated with risperidone plus furosemide was observed in two out of four clinical trials. No increased mortality rate was found in patients taking other diuretics as an adjunctive medication to risperidone.

No clear pathophysiological mechanism could be identified to explain this result. The cause of death was also not uniform. Nevertheless, caution should be exercised and the benefit-risk ratio of this combination or concomitant treatment with other potent diuretics should be weighed before use.

Regardless of treatment, dehydration has been a general risk factor for mortality and should therefore be carefully avoided in elderly dementia patients.

Increased cerebrovascular events

In placebo-controlled trials in elderly patients with dementia, the incidence of cerebrovascular events (insult and transient ischemic attacks [TIA]), including fatal outcomes, was significantly higher in patients treated with oral Risperdal compared to patients receiving placebo (mean age 85 years; Age range 73–97 years).

Orthostatic hypotension

The α1-lytic effect of risperidone may lead to (orthostatic) hypotension, especially during the initial dose adjustment. Caution is

Recommended in patients with known cardiovascular diseases (e.g. heart failure, myocardial infarction, conduction disorders, dehydration, hypovolemia or cerebrovascular diseases) (see "Adverse effects"). In acutely unstable cardiovascular situations (such as acute myocardial infarction), the administration of Risperdal Consta is not recommended.

In the case of persistent clinically relevant orthostatic hypotension, the benefit must be weighed against the risk of further treatment with Risperdal Consta.

Extension of the QT interval

In clinical trials, risperidone has not been associated with prolongation of the QTc interval. QT prolongation has been reported very rarely in the postmarketing phase. As with other antipsychotics, caution should be exercised when prescribing risperidone in patients with known cardiovascular disease and/or bradycardia, electrolyte imbalances (hypokalemia, hypomagnesemia), or a family history of QT prolongation. Caution should also be exercised in combination with other drugs that prolong the QT interval (see "Interactions").

Leukopenia, neutropenia and agranulocytosis

Cases of leukopenia, neutropenia, and agranulocytosis have been reported with the use of antipsychotics (including Risperdal Consta) in clinical trials and/or since marketing. Agranulocytosis has been observed very rarely (<1/10,000 patients) after marketing.

Patients with a history of clinically significant reduction in white blood cell counts or drug-induced leukopenia/neutropenia should be monitored during the first few months of therapy, and discontinuation of therapy with Risperdal Consta should be considered at the first sign of significant decline in white blood cells in the absence of other causal factors.

Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and should be treated immediately if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count

<1× 109/L) should discontinue therapy with Risperdal Consta and white blood cells should be monitored until recovery.

Venous thromboembolism

Cases of venous thromboembolism (VTE) have been reported in connection with the use of antipsychotics. Because patients treated with antipsychotics often have acquired risk factors for VTE, all possible risk factors for VTE should be identified and preventive measures taken before and during treatment with Risperdal Consta.

Tardive dyskinesia/extrapyramidal symptoms (EPS)

Drugs with antidopaminergic properties have been associated with the induction of tardive dyskinesia, which can manifest itself through rhythmic, involuntary movements, especially of the tongue and/or face. The appearance of extrapyramidal symptoms is a risk factor for tardive dyskinesias. If signs and symptoms of tardive dyskinesia occur, discontinuation of all antipsychotics should be considered.

Extrapyramidal symptoms and psychostimulants – Caution should be exercised in patients receiving both psychostimulants (e.g., methylphenidate) and risperidone at the same time, as extrapyramidal symptoms may occur when adjusting one or both drugs. Tapering off one or both treatments should be considered (see "Interactions").

Parkinson's disease and dementia with Lewy bodies

Caution should be exercised when Risperdal is prescribed with Lewy corpuscles in patients with Parkinson's disease or dementia. Risperdal may cause Parkinson's disease to worsen. Both groups may have an increased risk of neuroleptic malignant syndrome and increased sensitivity to antipsychotics (e.g., confusion, dulling of affect, balance disorder with frequent falls, in addition to extrapyramidal symptoms).

Neuroleptic malignant syndrome

In rare cases, antipsychotics lead to neuroleptic malignant syndrome, which manifests itself in hyperthermia, muscle rigidity, autonomic instability, changes in consciousness and increased serum creatine phosphokinase levels. Additional symptoms may include myoglobinuria (rhabdomyolysis) and acute renal failure. In this case, all antipsychotic drugs including Risperdal Consta should be discontinued. After the last administration of Risperdal Consta, risperidone plasma levels are still detectable for at least 6 weeks.

Hypersensitivity reactions

Although the tolerability of orally administered risperidone should be assessed before starting treatment with Risperdal Consta, anaphylactic reactions have occurred in very rare cases during post-marketing follow-up in patients who had previously tolerated orally administered risperidone (see "Dosage/Use" and "Adverse Effects"). Anaphylaxis symptoms include rash, hives, peripheral edema, swollen eyes, swollen tongue, swollen face, profuse sweating (hyperhidrosis), shortness of breath, and drop in blood pressure (hypotension).

Patients with hypersensitivity to oral risperidone, paliperidone or any of the other ingredients of the formulation or container should not be treated with Risperdal Consta (see "Contraindications").

If hypersensitivity reactions occur, the use of Risperdal Consta should be stopped; general supportive measures should be initiated depending on the clinical indication and the patient should be monitored until the signs and symptoms have subsided (see "Contraindications" and "Undesirable effects").

Hyperglycemia and diabetes mellitus

Hyperglycemia, diabetes mellitus, and exacerbation of pre-existing diabetes have been reported during treatment with Risperdal Consta. Assessment of the association between the use of atypical antipsychotics and glucose abnormalities is complicated by the possibility of an increased baseline risk of diabetes mellitus in schizophrenia patients and the increasing incidence of diabetes mellitus in the overall population. In light of these influencing factors, the association between the use of atypical antipsychotics and adverse effects associated with hyperglycaemia is not fully understood. However, epidemiological studies suggest an increased risk of hyperglycaemia-related adverse effects in patients treated with atypical antipsychotics. Any patient treated with atypical antipsychotics, including Risperdal Consta, should be monitored for symptoms of hyperglycaemia and diabetes mellitus.

Weight gain

Significant weight gain has been reported with the use of Risperdal Consta. Regular monitoring of the weight is therefore recommended.

Priapism

Drugs that cause α-adrenergic blockade have been reported to cause priapism. Priapism has been reported with Risperdal after the market launch (see section "Adverse effects").

Regulation of body temperature

Antipsychotics may interfere with the body's ability to lower core body temperature. Caution should therefore be exercised when prescribing Risperdal Consta to patients exposed to situations exposed to an increase in core body temperature (e.g., strenuous physical activity, exposure to extreme heat, concomitant use of anticholinergic drugs, or dehydration).

Antiemetic effect

In preclinical studies with Risperdone, an antiemetic effect was recorded. If this effect occurs in humans, it could mask signs and symptoms of overdose of certain substances or conditions such as intestinal obstruction, Reye's syndrome and brain tumour.

Epileptic seizures

Like all antipsychotics, Risperdal Consta should be used cautiously in patients with a history of epileptic seizures or other conditions that may be associated with a lowering of the seizure threshold.

Intraoperative floppy iris syndrome

Cases of intraoperative floppy iris syndrome (IFIS) have been observed in cataract surgery on patients treated with drugs with alpha1a-adrenergic antagonistic activity, including Risperdal Consta.

The IFIS can increase the risk of complications of the eye during and after surgery. Prior to surgery, the ophthalmic surgeon should be informed of any current or previous use of drugs with alpha1a-adrenergic antagonistic effect. The potential benefit of discontinuing therapy with alpha1 antagonists prior to cataract surgery has not been studied and must be weighed against the risk of discontinuation of antipsychotic therapy.

Prolactin-dependent tumors

Risperdal Consta should only be used with special caution in the presence of prolactin-dependent tumors, e.g. prolactinomas of the pituitary gland and possibly prolactin-dependent tumors, e.g. epithelial breast tumors.

Administration

Care must be taken to ensure that Risperdal Consta is not accidentally injected into a blood vessel (see "Adverse effects – Retinal artery occlusion").

This medicine contains less than 1 mmol of sodium (23 mg) per injection, i.e. it is almost "sodium-free".

Interactions

The interactions of Risperdal Consta with the concomitant use of other medicinal products have not been systematically studied. The interactions described in this section are based on studies with oral risperidone.

Pharmacokinetic interactions

Risperidone is metabolized primarily by CYP2D6 and, to a lesser extent, by CYP3A4. Both risperidone and its active metabolite 9-hydroxyrisperidone are substrates of P-glycoprotein (P-gp). Modifiers of CYP2D6 activity or strong inhibitors or inducers of the activity of CYP3A4 and/or P-gp may affect the pharmacokinetics of the active antipsychotic fraction of risperidone.

Pharmacodynamic Interactions Centrally

Acting Drugs and Alcohol

In view of the primary CNS effects of Risperdal, combined use with other centrally acting drugs or alcohol should be carried out with caution.

Levodopa and dopamine agonists

Risperidone may reduce the effect of levodopa and other dopamine agonists. If this combination is deemed necessary, especially in the final stages of Parkinson's disease, the lowest effective dose should be prescribed with each treatment.

Psychostimulants

The use of psychostimulants (e.g. methylphenidate) in combination with risperidone can lead to the occurrence of extrapyramidal symptoms if one or both treatments are changed (see "Warnings and precautions").

Drugs with hypotensive action

Post-marketing, clinically significant hypotension has been observed with concomitant use of risperidone and antihypertensive drugs.

Medicinal products with known QT-prolonging effects

Caution should be exercised when prescribing Risperdal Consta with medicines known to prolong the QT interval.

Enzyme Inducers

CYP3A4 and/or P-gp inductors

When Risperdal Consta is used together with a strong CYP3A4 and/or P-gp inducer, the plasma concentration of the active antipsychotic fraction of risperidone may decrease. When initiating or stopping concomitant use of carbamazepine or any other potent CYP3A4 and/or P-gp inducer, the dosage of Risperdal Consta should be reassessed by the physician.

Enzyme inhibitors

Potent CYP2D6 inhibitors

When Risperdal Consta and a strong CYP2D6 inhibitor are used together, the plasma concentration of risperidone may increase, but the active antipsychotic fraction is less affected. Potent CYP2D6 inhibitors at higher doses may increase the concentration of the active antipsychotic fraction of risperidone (e.g., paroxetine, see below). When initiating or stopping concomitant use of paroxetine, bupropion, or any other potent CYP2D6 inhibitor, especially at higher doses, the dosage of Risperdal Consta should be reassessed by the physician.

CYP3A4 and/or P-gp inhibitors

When Risperdal Consta and a potent CYP3A4 and/or P-gp inhibitor are used together, the plasma concentration of the active antipsychotic fraction of risperidone may increase significantly. When initiating or stopping concomitant use of itraconazole or any other potent CYP3A4 and/or P-gp inhibitor, the dosage of Risperdal Consta should be reassessed by the physician.

Other interactions

Highly protein-bound substances

When Risperdal Consta and drugs that are highly protein-bound are used together, there is no clinically significant displacement of plasma proteins in any of the active substances.

If concomitant medication is used, the information on the type of metabolisation and on the possible need for dose adjustment in the respective medicinal product information must be observed.

Pediatric Patients

Interaction studies were conducted only in adults. The relevance of the results of these studies for pediatric patients is not known.

Examples

The following are examples of medicines that may or may not interact with risperidone:

Effect of Risperdal Consta on other medicines

Anticonvulsive:

- Risperidone has no clinically meaningful effect on the pharmacokinetics of valproate or topiramate.

Lithium:

- Risperidone has no clinically meaningful effect on the pharmacokinetics of lithium.

Effect of other medicines on Risperdal Consta

Antibacterial substances:

- Erythromycin, a moderate CYP3A4 inhibitor, does not alter the pharmacokinetics of risperidone and the active antipsychotic fraction.
- Rifampicin, a potent CYP3A4 inducer and P-gp inducer, decreases the plasma concentration of the active antipsychotic fraction.

Anticholinesterases:

- The cholinesterase inhibitors galantamine and donepezil, both of which are substrates of CYP2D6 and CYP3A4, have no clinically meaningful effect on the pharmacokinetics of risperidone and the active antipsychotic fraction.

Anticonvulsive:

- Carbamazepine, a potent CYP3A4 inducer and P-gp inducer, decreases the plasma concentration of the active antipsychotic fraction of risperidone.
- Topiramate results in a moderate reduction in the bioavailability of risperidone, but does not affect the bioavailability of the active antipsychotic fraction. This interaction is therefore unlikely to be clinically significant.

Antifungals:

- Itraconazole, a potent CYP3A4 inhibitor and P-gp inhibitor, increased the plasma concentration of the active antipsychotic fraction by about 70% at doses of 200 mg/day and at risperidone doses of 2 to 8 mg/day.

- Ketoconazole, a potent CYP3A4 inhibitor and P-gp inhibitor, increased the plasma concentration of risperidone and decreased the plasma concentration of 9-hydroxyrisperidone at the dosage of 200 mg/day.

Antipsychotics:

- Phenothiazines may cause an increase in the plasma concentration of risperidone, but have no effect on the plasma concentration of the active antipsychotic fraction.
- For aripiprazole, a substrate of CYP2D6 and CYP3A4, there is insufficient clinical evidence to assess a possible effect of risperdal on the pharmacokinetics of aripiprazole and its active metabolite dehydroaripiprazole.

Virostatics:

- Protease inhibitors: No formal study data are available. However, since ritonavir is a potent CYP3A4 inhibitor and a weak CYP2D6 inhibitor, ritonavir and ritonavir-boosted protease inhibitors have the potential to increase the concentration of the active antipsychotic fraction of risperidone.

Beta-blockers:

- Some beta-blockers may lead to an increase in the plasma concentration of risperidone, but have no effect on the plasma concentration of the active antipsychotic fraction.

Calcium channel blockers:

- Verapamil, a moderate inhibitor of CYP3A4 and inhibitor of P-gp, increases the plasma concentration of risperidone and the active antipsychotic fraction.

Digitalis glycosides:

- Risperidone has no clinically meaningful effect on the pharmacokinetics of digoxin.

Diuretics:

- Furosemide: The information in the Warnings *and precautions for* increased mortality in elderly patients with dementia receiving adjunctive treatment with furosemide should be observed.

Gastrointestinal medicines:

- H2 receptor antagonists: Cimetidine and ranitidine, both of which are weak inhibitors of CYP2D6 and CYP3A4, increased the bioavailability of risperidone, but only marginally increased that of the active antipsychotic fraction.

SSRIs and tricyclic antidepressants:

- Fluoxetine, a potent CYP2D6 inhibitor, increases the plasma concentration of risperidone, but the active antipsychotic fraction is less affected.
- Paroxetine, a potent CYP2D6 inhibitor, increases the plasma concentration of risperidone, but at doses up to 20 mg/day, the active antipsychotic fraction is less affected. However, at higher doses of paroxetine, the concentration of the active antipsychotic fraction of risperidone may increase in a dose-dependent *manner* .
- Tricyclic antidepressants may lead to an increase in the plasma concentration of risperidone, but have no effect on the plasma concentration of the active antipsychotic fraction. Amitriptyline has no effect on the pharmacokinetics of risperidone or the active antipsychotic fraction.
- Sertraline, a weak inhibitor of CYP2D6, and fluvoxamine, a weak inhibitor of CYP3A4, do not produce clinically significant changes in the concentration of the active antipsychotic fraction of risperidone at doses up to 100 mg/day. However, in sertraline or fluvoxamine doses above 100 mg/day, the concentration of the active antipsychotic fraction of risperidone may increase.

Pregnancy, breastfeeding

Pregnancy

The safety of risperidone when used during pregnancy has not been studied.

A retrospective observative cohort study based on a U.S. database of billed health care services compared the risk of congenital malformations in live births between women with and without antipsychotic use in the first trimester of pregnancy. The risk of congenital malformations with the use of risperidone was increased after adjustment for confounding variables in the database compared to the non-use of antipsychotics (relative risk = 1.26, 95% CI: 1.02-1.56). No biological mechanism has been identified to explain this finding, and no teratogenic effects have been observed in preclinical studies. Based on the results of this individual observative study, no causal relationship was identified between risperidone exposure *in utero* and congenital malformations.

Although risperidone did not show any direct reproductive toxicity in animal studies, some indirect prolactin and CNS-mediated effects were observed (see section "Preclinical data").

Risperdal Consta must not be used during pregnancy unless absolutely necessary. If it is necessary to discontinue treatment during pregnancy, this should not be done abruptly.

Third trimester

Newborns whose mothers took antipsychotics (including risperidone) during the third trimester of pregnancy are at risk of extrapyramidal and/or withdrawal symptoms after birth. These symptoms in newborns may include agitation, abnormally increased or decreased muscle tone, tremor, drowsiness, difficulty breathing, or problems feeding. These complications can vary in severity. In some cases, they were self-limiting, in other cases the newborns required monitoring in the intensive care unit or prolonged hospitalization.

Nursing period

In animal studies, risperidone and 9-hydroxy-risperidone were excreted with milk. Risperidone and 9-hydroxy-risperidone have also been shown to pass into human breast milk. In one individual case, it was measured that 4.3% of the active antipsychotic fraction (reference maternal dose) appears in breast milk. Therefore, mothers who are treated with risperidone should not breastfeed.

Effect on driving ability and on the operation of machines

Risperdal Consta may have an adverse effect on activities that require concentration and mental alertness. Patients should therefore be advised not to drive vehicles or operate complicated machines until their individual ability to react has been clarified and the attending physician has discussed and explained the corresponding assessment with the patient.

Undesirable effects

The most commonly reported adverse reactions (frequency ≥1/10) are: insomnia, anxiety, headache, upper respiratory tract infection, parkinsonism, and depression.

Paliperidone is the active metabolite of risperidone. Therefore, the adverse reaction profiles of both substances (including their oral and injectable formulations) are of mutual relevance. Below is a complete list of adverse reactions reported in clinical trials and post-marketing with risperidone and/or paliperidone. The following terms and frequencies are used: very common (≥1/10), common (≥1/100 to <1/10), occasional (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) and unknown (frequency cannot be estimated on the basis of available data).

Within each frequency group, the side effects are reported in order of decreasing severity.

Adverse reactions by system organ class and frequency:

Infections and parasitic diseases

Very common: infections of the upper respiratory tract.

Common: pneumonia, bronchitis, sinusitis, urinary tract infection, influenza.

Uncommon: respiratory tract infection, cystitis, ear infection, eye infection, tonsillitis, onychomycosis, cellulitis, infection, localized infection, viral infection, acarodermatitis, subcutaneous abscess.

Diseases of the blood and lymphatic system Common:

anemia.

Uncommon: decrease in white blood cell count, thrombocytopenia, decrease in hematocrit.

Rare: neutropenia.

Not known: agranulocytosis, decrease in the number of eosinophilic granulocytes.

Immune system disorders Uncommon:

hypersensitivity.

Not known: anaphylactic reaction.

Endocrine diseases

Common: hyperprolactinemia.

Rare: inadequate secretion of antidiuretic hormone.

Metabolic and nutritional disorders

Common: hyperglycemia, weight gain, increased appetite, weight loss, decreased appetite.

Uncommon: diabetes mellitusb, anorexia, triglycerides increased, cholesterol increased, glucosuria.

Rare: hypoglycemia, polydipsia.

Very rare: diabetic ketoacidosis.

Not known: water intoxication, hyperinsulinemia, diabetic coma.

Psychiatric disorders

Very common: insomnia, depression, anxiety.

Common: sleep disturbance, agitation, decreased libido.

Uncommon: mania, confusion, anorgasmia, nightmares. *Rare:*

catatonia, somnambulism, blunted affect.

Not known: Sleep-related eating disorder (uncontrolled eating during sleepwalking).

Diseases of the nervous system

Very common: parkinsonism, headache.

Common: akathisiec, somnolence, dystoniac dizziness, dyskinesia[c], tremor.

Occasionally: Cerebrovascular Ischemia Loss of consciousness convulsions, Syncope Tardive Dyskinesia Psychomotor Hyperactivity, balance disorder, postural vertigo, attention disorder, dysarthria, taste disorder, hypoesthesia, paresthesia.

Rare: neuroleptic malignant syndrome, reduction in consciousness, head tremors.

Not known: Lack of stimulus response.

Eye disorders

Common: blurred vision.

Uncommon: conjunctivitis, dry eye, increased tear secretion, ocular hyperemia.

Rare: Eye movement disorder, eye rolling, photophobia.

Not known: retinal artery occlusion, glaucoma, crusting of the eyelid margin, floppy iris syndrome (intraoperatively).

Diseases of the ear and labyrinth Uncommon: vertigo,

tinnitus, earache.

Heart disease common:

tachycardia.

Uncommon: atrial fibrillation, atrioventricular block, conduction disorder, prolonged QT interval on electrocardiogram, baradycardia, abnormal electrocardiogram, palpitations.

Rare: sinus arrhythmias.

Not known: postural orthostatic tachycardia syndrome.

Vascular diseases

Common: hypotension, hypertension.

Uncommon: Orthostatic hypotension. *Rare:*

pulmonary embolism, deep vein thrombosis.

Not known: Flush.

Diseases of the respiratory, thoracic cavity and mediastinum

Common: dyspnea, pharyngolaryngeal pain, cough, nasal congestion.

Uncommon: hyperventilation, airway obstruction, wheezing, epistaxis.

Rare: sleep apnea syndrome, aspiration pneumonia, pulmonary congestion, lung rattling, dysphonia, breathing disorder.

Diseases of the gastrointestinal tract

Common: abdominal discomfort, vomiting, nausea, constipation, gastroenteritis, diarrhea, dyspepsia, dry mouth, toothache.

Uncommon: faecal incontinence, dysphagia, flatulence.

Rare: pancreatitis, intestinal obstruction.

Very rare: ileus.

Not known: swollen tongue, faeculoma, cheilitis.

Liver and Biliary Diseases

Common: transaminases increased, increased gamma-glutamyl transferase levels.

Uncommon: Liver enzyme levels elevated.

Rare: Jaundice.

Diseases of the skin and subcutaneous tissue

Common: rash.

Uncommon: pruritus, alopecia, eczema, dry skin, erythema, skin discoloration, acne, seborrheic dermatitis.

Rare: Drug eruption, urticaria, hyperkeratosis, skin diseases, skin lesions.

Very rare: angioedema.

Not known: Stevens-Johnson syndrome/toxic epidermal necrolysis.

Skeletal muscle, connective tissue and bone diseases

Common: muscle cramps, musculoskeletal pain, back pain, arthralgia.

Uncommon: increased creatine phosphokinase level, joint stiffness, swelling of the joints, muscle weakness, neck pain.

Rare: rhabdomyolysis, abnormal posture.

Diseases of the kidneys and urinary tract

Common: urinary incontinence.

Uncommon: pollakiuria, urinary retention, dysuria.

Pregnancy, postpartum and perinatal diseases

Very rare: Extrapyramidal motor symptoms and/or withdrawal symptoms in the newborn.

Diseases of the genital organs and mammary gland Common:

erectile dysfunction, amenorrhea, galactorrhea.

Uncommon: ejaculation disorder, delayed menstruation, menstrual disorderc, gynecomastia, sexual dysfunction, breast discomfort, vaginal discharge.

Rare: Swelling of the mammary gland, secretion from the mammary gland.

Not known: priapism.

Injury, poisoning and complications caused by procedures Common:

fall.

Uncommon: administration-related pain.

General diseases and administration site complaints

Common: edema, pyrexia, chest discomfort, asthenia, fatigue, pain, pain at the injection site, fall.

Uncommon: facial edema, chills, increased body temperature, abnormal gait, thirst, feeling ill, abnormal feeling, induration.

Rare: hypothermia, discomfort.

Very rare: Anaphylactic reaction after injection with Risperdal Consta in patients who have previously tolerated oral risperidone.

Not known: decreased body temperature, peripheral feeling of cold, drug withdrawal syndrome.

[a] Hyperprolactinemia can lead to gynecomastia, menstrual irregularities, amenorrhea, and galactorrhea in some cases.

[b] In placebo-controlled trials, diabetes mellitus was reported in 0.18% of patients treated with risperidone, compared to 0.11% in the placebo group. The overall incidence from all clinical trials was 0.43% in all patients treated with risperidone.

[c] *Insomnia* includes: initial sleep disorder, difficulty sleeping through the night;

Parkinsonism includes: akinesia, bradykinesia, gear phenomenon, salivation, extrapyramidal motor symptoms, pathological glabellar reflex, muscle stiffness, muscle tension, musculoskeletal stiffness;

Akathisia includes: hyperkinesia, restless legs syndrome, restlessness;

Dystonia includes: blepharospasm, cervical spasms, emprosthotonus, facial spasm, muscle hypertension, laryngospasm, involuntary muscle contractions, myotonia, oculogyration, opisthotonus, oropharyngeal spasm, pleurothotonus, risus sardonicus, tetany, tongue paralysis, tongue spasm, torticollis, trismus;

Dyskinesia includes: athetosis, chorea, choreoathetoid movements, movement disorders, muscle twitching, myoclonus;

Convulsions include: grand mal seizures;

Edema includes: generalized edema, peripheral edema, edema with indentable dents ("pitting edema");

Menstrual disorders include: irregular menstruation, oligomenorhoea.

Description of selected adverse reactions Class effects

Extension of the QT interval

As with other antipsychotics, very rare cases of QT prolongation have been reported with risperidone after marketing. Other class-related cardiac effects reported among antipsychotics that prolong the QT interval include ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia, sudden death, cardiac arrest, and torsades de pointes. (see section "Warnings and precautions").

Weight gain

In a 12-week, double-blind, placebo-controlled study, 9% of patients treated with Risperdal Consta experienced a weight gain of ≥7% of body weight at the endpoint of the study, compared to 6% of patients treated with placebo. During the 1-year open-label study of Risperdal Consta, changes in body weight in individual patients were generally within ±7% of baseline weight; in 25% of the patients, there was an increase in body weight of ≥7%.

Reporting suspected side effects after approval is of great importance. It enables continuous monitoring of the benefit-risk ratio of the drug. Healthcare professionals are encouraged to report any suspicion of a new or serious adverse reaction via the ElViS (Electronic Vigilance System) online portal. You can find information about this under www.swissmedic.ch.

Overdosing

There is only experience with the oral form:

Signs and symptoms

The expected symptoms consist of an expansion of the known pharmacological effects. These include lightheadedness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. In overdoses, rare cases of QT prolongation have been observed and convulsions have been observed. Cases of torsade de pointes have been reported in association with concomitant overdose of risperdal and paroxetine.

Treatment

In the event of an overdose, the airways must be cleared and kept clear and sufficient oxygen supply and ventilation must be ensured. The heart and circulation must be monitored immediately. Continuous ECG monitoring is required to detect any arrhythmias.

There is no specific antidote for Risperdal Consta. Appropriate measures must therefore be prepared. In the case of acute overdose, the possibility of multiple drug involvement should be considered. Hypotension and circulatory collapse should be treated with appropriate measures, such as intravenous infusion and/or sympathomimetic drugs. In severe extrapyramidal symptoms, an anticholinergic drug should be administered. Close medical monitoring should be continued until the patient recovers.

Properties/Effects

ATC code

N05AX08

Action

Risperdal Consta (risperidone) is an antipsychotic drug that belongs to a new class – the benzisoxazole derivatives. It has a high affinity for the dopaminergic D2 and the serotonergic $5HT_2$ receptors. Risperidone also occupies the α 1-adrenergic and, with lower affinity, the

histaminergic H1 and the adrenergic α2 receptors. Risperidone has no affinity for the cholinergic receptors. Although risperidone is a potent D2 antagonist, which is known to reduce the positive symptoms of schizophrenia, it is less dampening motor activity

and triggers catalepsy to a lesser extent than the classic neuroleptics. The balanced central serotonin and dopamine antagonism reduces the likelihood of extrapyramidal side effects and extends the therapeutic effect to the negative and affective symptoms of schizophrenia as well.

The efficacy of Risperdal Consta (25 mg and 50 mg) in the treatment of psychotic disorders (schizophrenia, schizoaffective disorder) was demonstrated in a 12-week, placebo-controlled study in psychotic inpatients and outpatients who met the criteria for schizophrenia according to DSM-IV.

A 12-week comparative study in schizophrenia patients with stable symptoms showed that Risperdal Consta was as effective as the oral tablet formulation.

The efficacy and safety of Risperdal Consta with long-term treatment (50 weeks) was evaluated in an open-label study in psychotic inpatients and outpatients with stable symptoms who met the DSM-IV criteria for schizophrenia or schizoaffective disorder. During this time, the effect of Risperdal Consta was maintained. (This study did not have a comparison group.)

Pharmacodynamics

See mechanism of action

Clinical efficacy

See *Mechanism of Action*

Pharmacokinetics *Release*

After a single intramuscular administration of Risperdal Consta, a small amount of active ingredient (<1% of the dose) is initially released, followed by a 3-week lag period. The main release begins from the 3rd week. The quantity released is maintained during the 4-6th week and decreases again from the 7th week onwards. During the first 3 weeks of therapy with Risperdal Consta, an additional antipsychotic must therefore be given. In the clinical trials, risperidone tablets were used during the first three weeks.

The combination of the release profile and the injection interval (intramuscular injection every other week) leads to the maintenance of therapeutic plasma concentrations. Therapeutic concentrations persist until 4–6 weeks after the last injection.

Elimination is completed 7-8 weeks after the last Risperdal Consta administration.

Absorption

Risperidone is completely absorbed after release.

Distribution

Risperidone is distributed quickly. The apparent volume of distribution (Vd) is 1–2 l/kg. The plasma protein binding to albumin and acid α1-glycoprotein of risperidone is 88%, that of the active metabolite of 9-hydroxy-risperidone is 77%.

The mean minimum and maximum plasma concentrations of the active antipsychotic fraction obtained after repeated intramuscular injection of 25 mg and 50 mg of Risperdal Consta at intervals of 2 weeks were 9.9 and 19.2 ng/ml and 17.9 and 45.5 ng/ml, respectively. The pharmacokinetics of risperidone are linear in the dose interval 25 to 50 mg with an injection interval of two weeks. In long-term use (12 months), no accumulation of risperidone was observed in patients who received an injection of 25–50 mg every two weeks.

The studies mentioned were conducted with gluteal intramuscular injection. Deltoid and gluteal intramuscular injections with the same dose are bioequivalent and therefore interchangeable.

Metabolism

Risperidone is metabolized predominantly in the liver via CYP 2D6. It is mainly used to 9-hydroxy-risperidone, which has a similar

pharmacological effect such as risperidone. Risperidone and 9-hydroxy-risperidone together form the active antipsychotic fraction.

The CYP 2D6 has a genetic (debrisoquine/dextromethorphan) polymorphism. Fast metabolizers quickly convert risperidone into 9-

Hydroxy-risperidone, while slow metabolizers do so more slowly. Fast metabolizers therefore have lower risperidone and higher 9-hydroxy-risperidone concentrations in plasma than slow metabolizers. Since risperidone and 9-hydroxy-risperidone have about the same antipsychotic activity, the sum of their concentrations is decisive. For this reason, no clinically relevant differences were observed in slow and fast metabolizers.

A less important degradation pathway is N-dealkylation, which probably occurs via CYP3A4.

Elimination

The clearance of the active antipsychotic fraction and risperidone respectively is 5.0 and 13.7 l/h for fast metabolizers (for CYP 2D6) and 3.2 and 3.3 l/h for slow metabolizers, respectively.

Kinetics of special patient groups

Higher active plasma levels (Cmax was approximately 1.1 and 1.5 times higher and AUC was approximately 1.5 and 2.5 times higher) were observed in elderly and renal insufficiency patients after oral administration. This probably reflects a 30% decrease in clearance of the active antipsychotic fraction in elderly patients and a 60% reduction in renal insufficiency patients. Plasma risperidone concentrations were within the normal range in patients with hepatic insufficiency, but the mean plasma free risperidone fraction was increased by about 35%.

Specific pharmacokinetic studies with Risperdal Consta are not available in these patient groups. However, pharmacokinetic analyses suggest that at the recommended dosage of 25 mg every 2nd week, plasma concentrations in elderly patients (>65 years) and in patients with mild to moderate renal insufficiency are within the range observed in adults. The analyses are based on the active ingredient concentrations determined in the Phase III studies with Risperdal Consta (see "Special dosing instructions").

Relationship between pharmacokinetics and pharmacodynamics

In none of the Phase III studies investigating efficacy and safety was there an association between plasma concentrations of the active antipsychotic fraction and the change in total scores according to PANSS (Positive and Negative Syndrome Scale) or ESRS (Extrapyramidal Symptom Rating Scale).

Preclinical data

In repeated dose toxicity studies in rats and dogs, mainly pharmacological effects, such as sedation and prolactin-mediated effects on the mammary glands and genitals, have been observed.

Mutagenicity

Risperidone was not genotoxic in the standard tests.

Carcinogenicity

As expected for a potent D2 antagonist, an intramuscular carcinogenicity study in rats showed a prolactin effect at 40 mg/kg.

mediated increased incidence of endocrine tumors of the pancreas, pituitary gland, and adrenal medulla. Mammary gland carcinomas occurred at 5 and 40 mg/kg. Hypercalcemia, which is postulated to lead to an increased incidence of tumors of the adrenal medulla, was observed in both dose groups. In male rats, tubular renal adenomas occurred. At the low dose, the NaCl 0.9% or the microsphere control group, no kidney tumors occurred. The mechanism for the development of renal tumors in rats treated with Risperdal Consta is unknown. In the oral carcinogenicity studies in rats or with oral administration of risperidone in mice, there was no treatment-dependent increase in renal tumor incidence.

Reproductive toxicity

Although no direct reproductive disorders have been found with risperidone in animal studies, indirect prolactin-mediated effects have been observed.

Risperidone showed no teratogenic effects in rats and rabbits.

In rats, negative effects on mating behavior, birth weight and survival of the offspring were observed. Behavioral disorders in the offspring have not been investigated.

Other notes

Incompatibilities

Risperdal Consta must not be mixed with any other solution or medicinal product other than the solution supplied for the preparation of the suspension.

Durability

The medicine must only be used up to the date marked "EXP" on the container.

Shelf life after opening

The chemical and physical stability of the suspension is guaranteed at 25 °C for 24 hours after preparation. From a microbiological point of view, however, the suspension should be used immediately after preparation. If the suspension is not administered immediately, the responsibility for the storage time and storage conditions lies with the user. This should normally not exceed 6 hours at 25 °C, unless the preparation was carried out under controlled and validated aseptic conditions.

Special storage instructions

Store the entire package in the refrigerator (2-8 °C).

If a refrigerator is not available, Risperdal Consta can be stored at temperatures that do not exceed 25 °C for a maximum of 7 days before application. Do not expose to temperatures above 25 °C.

Store the container in the outer carton to protect the contents from light. Keep out

of reach of children!

Instructions for handling

For Risperdal Consta, it is important to follow the "Instructions for Handling" step by step to ensure successful administration and to avoid difficulties in using the kit.

The delayed-release microspheres (powder in the vial) of Risperdal Consta must *only* be suspended from the pre-filled syringe in the solution supplied. Only the appropriate injection needle enclosed in the package for gluteal (2-inch needle, 51 mm) or deltoid (1-inch needle, 25 mm) injection may be used for injection. Do not replace any of the elements of the injection kit.

To ensure that the intended dose of risperidone is released, the entire contents of the vial must be administered. If the contents are partially administered, the intended dose of risperidone may not be released. It is recommended that administration be carried out immediately after reconstitution.

Remove the Risperdal Consta pack from the refrigerator and wait about 30 minutes to make the suspension until it has reached room temperature.

Contents of the injection kit

- A vial of sustained-release microspheres.
- A pre-filled syringe with solvent.
- A vial adapter for attaching the pre-filled syringe (connector for making the suspension).
- Two Terumo SurGuard-3® hypodermic needles for intramuscular injection (a 21G UTW 1-inch safety hypodermic needle (25 mm) with needle protection unit for deltoid injection and a 20G TW 2-inch safety hypodermic needle (51 mm) with needle protection unit for gluteal injection).

Instructions for use, handling and disposal Important

notes

For a successful administration of Risperdal Consta, please follow these step-by-step instructions for use carefully.

Wait 30 minutes

Remove the individual pack from the refrigerator and let it sit at room temperature for at least 30 minutes before starting the reconstitution.

Do not heat in any other way.

Use included components

The ingredients contained in the single-dose pack are specifically intended for use with Risperdal Consta. Risperdal Consta must only be reconstituted with the solvent supplied in the single-dose pack.

DO NOT replace any components of this single-dose pack. Do not
store reconstituted suspension.

Administer dose after reconstitution as soon as possible to avoid discontinuation.

Correct dosage

To ensure that the intended dose of Risperdal Consta is administered, the entire contents of the vial must be administered.

SINGLE-USE MEDICAL DEVICE

Do not reuse. Medical devices require specific material properties to perform as intended. These properties have only been tested for single use. Attempts to reprocess the medical device for subsequent reuse can adversely affect the integrity of the product or lead to reduced functionality.

Step 1.

Remove the single-dose pack from the refrigerator and let it sit at room temperature for at least 30 minutes before starting the reconstitution. Do not heat in any other way.

Connect the vial adapter *to the vial Remove the cap from the vial*

Remove the colored cap from the vial. Wipe the top of the gray stopper with an alcohol swab. Leave it on
air dry. Do not remove the grey rubber plug (Fig. A).

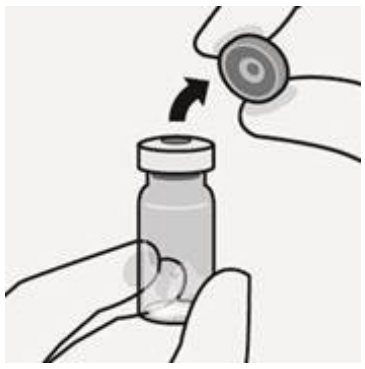

Fig. A

Preparation of the vial adapter

Hold the sterile blister as shown (Fig. B). Peel off the protective paper. Do not remove the device from the blister. The spike must not be touched at any time. This would lead to contamination.

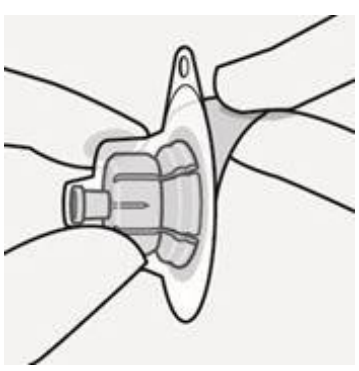

Fig. B

Connect the vial adapter to the vial

Place the vial on a firm surface and hold it in the lower area. Hold the vial adapter centrally over the gray rubber stopper. Press the vial adapter straight down onto the top of the vial until it clicks securely into place (Fig. C).



Fig. C

Do not place the vial adapter at an angle, otherwise solvent may leak out when transferring it into the vial (Fig. D).



Fig. D

Connect the pre-filled syringe to the vial adapter Remove

the sterile blister

Do not remove the vial adapter from the sterile blister until you are ready to remove the white cap from the pre-filled syringe. Hold the vial upright to prevent leakage. Hold the vial at the bottom and pull the sterile blister upwards.

Do not shake.

Do not touch the exposed Luer connector onto the vial adapter. This would lead to contamination (Fig. E).



Fig. E

Hold correctly

Hold the syringe by the white cuff at the tip. Do not hold the syringe by the glass cylinder when assembling it (Fig. F).

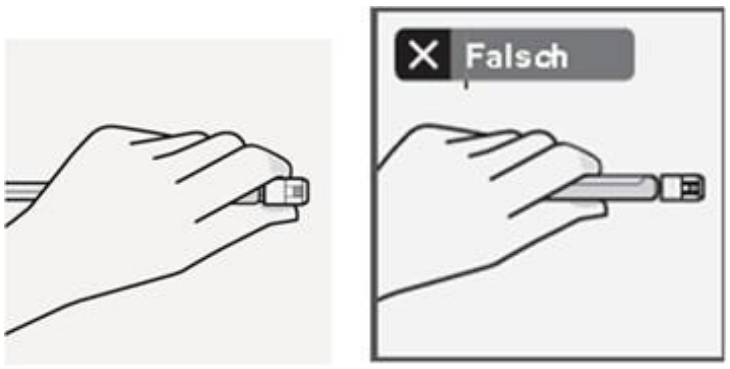

Fig. F

Remove cap

Hold the white cuff and bend off the white cap.

Do not touch the tip of the syringe. This would lead to contamination.

When the cap has been removed, the syringe will look like Fig. G. The broken cap can be disposed of.



Fig. G

Connect the syringe to the vial adapter

Hold the vial adapter in place on the jacket.

Hold the syringe by the white cuff and then insert the tip into the luer port on the vial adapter (Fig. H).



Fig. H

Do not hold the syringe to the glass cylinder. This can cause the white cuff to loosen or peel off. Connect the syringe to the vial adapter with a vigorous clockwise twist until it is firmly seated. Do not overexcite. Over-tightening can result in the syringe tip breaking off.

Step 2: Reconstitute microspheres, inject

solvent

Inject all the solvent from the syringe into the vial.

The contents of the vial are now under pressure. Continue to hold down the syringe plunger with your thumb (Fig. I).

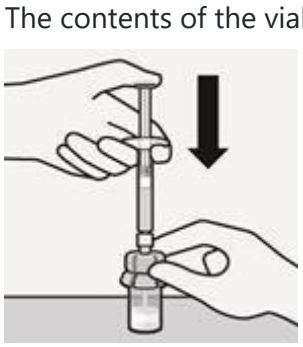

Fig. I

Suspending microspheres in the solvent

While continuing to hold down the syringe plunger, shake the syringe and vial vigorously for at least 10 seconds (Fig. J).



Fig. J

Check the suspension. Once a good mixture is achieved, the suspension appears homogeneous, thick and milky. The microspheres become visible in the liquid. Immediately proceed to the next step so that the suspension does not settle.

Transfer suspension to syringe

Turn the vial upside down. Slowly withdraw the syringe plunger to draw up all the contents from the vial into the syringe (Fig. K).

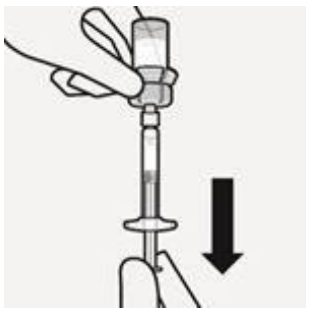

Fig. K

Remove vial adapter

Hold the white cuff of the syringe and twist it off the vial adapter. Peel off the peelable section of the vial label at the perforation. Attach the peeled label to the syringe for identification (Fig. L).

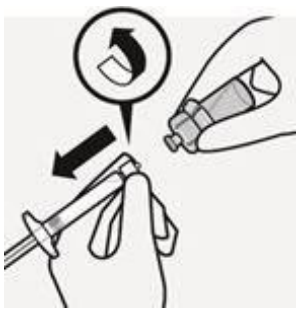

Fig. L

Dispose of the vial and vial adapter properly.

Step 3 Attach the needle

Select the right needle

Select the needle according to the injection site (gluteal or deltoidal) (Fig. M).

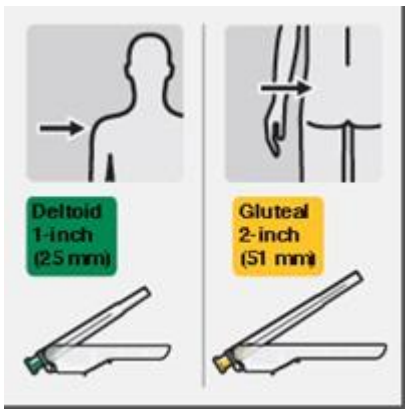

Fig. M

Attach the needle

Pull the blister pack halfway open and use it as shown (Fig. N) to grasp the needle at the base.



Fig. N

While holding the white syringe cuff, attach the needle's Luer connector to the syringe with a vigorous clockwise twist until it is firmly in place.

Do not touch the Luer connector of the needle. This would lead to contamination.

Resuspend Microspheres

Remove the blister completely. Shake the syringe vigorously again immediately before the injection, as some microspheres may have settled (Fig. O).

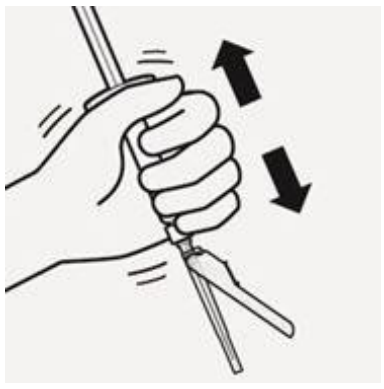

Fig. O

Step 4. Inject Dose

Remove transparent needle cap

Move the needle safety device back as shown. Then hold the white cuff of the syringe firmly and carefully pull off the transparent needle cap straight (Fig. P).

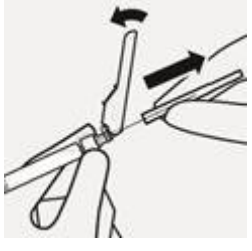

Fig. P

Do not twist off the transparent needle cap, as this may loosen the Luer connection.

Remove air bubbles

Hold the needle upright and tap gently to allow air bubbles to rise upwards. Slowly and carefully push the syringe plunger upwards to remove the air (Fig. Q).



Fig. Q

Inject

Immediately inject the entire contents of the syringe intramuscularly (i.m.) into the patient's gluteal or deltoid muscle. Gluteal injection should be given into the upper outer quarter of the gluteal region (Fig. R).

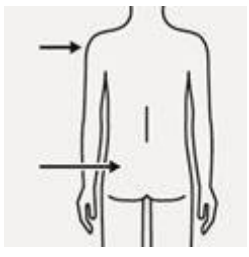

Fig. R

Do not administer intravenously.

Secure the needle in the safety device

Hold the needle safety device with one hand at a 45-degree angle against a firm, flat surface. Press it down with a strong, quick motion until the needle is fully engaged in the needle safety device (Fig. S).

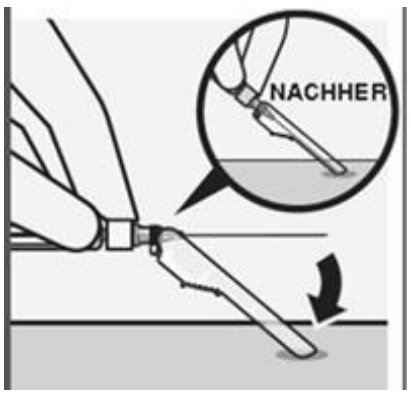

Fig. S

Avoid needlestick injuries:

- Do not use both hands.
- Do not intentionally loosen the needle safety device or use it improperly.
- Do not attempt to straighten the needle or engage the safety device if the needle is bent or damaged.

Proper disposal of needles

Make sure that the needle safety device is fully engaged. Dispose of syringe and needle in a proper syringe container.

Also discard the unused needle supplied in the single-dose pack (Fig. T).



Fig. T ***authorisation number*** 56092

(Swissmedic).

Packs

Risperdal Consta injection kit with vial 25 mg and pre-filled syringe with solvent. [B] Risperdal Consta Injection Kit with 37.5 mg vial and pre-filled syringe with solvent. [B] Risperdal Consta Injection Kit with 50 mg vial and pre-filled syringe with solvent. [B]

Each pack contains 1 vial adapter for reconstitution and 2 Terumo SurGuard-3® injection needles (one 21G UTW 1-inch safety needle (25 mm) with protective sleeve for deltoid injection and one 20G TW 2-inch needle (51 mm) with protective sleeve for gluteal injection).

Marketing authorisation holder

Janssen-Cilag AG, Zug,

ZG. ***Status of information***

September 2020

Contents of the single-dose pack



