



31 Mar 2015

**Ultravist (iopromide)**

**- Reminder for Precautions on Hypersensitivity-**

Dear Healthcare Professional,

Bayer HealthCare would like to inform you of the following:

**Summary**

**Cases of hypersensitivity including international fatal cases have been reported with the use of Ultravist (iopromide). This letter aims to advise HCP on the precautionary recommendations on hypersensitivity reactions and to initiate timely and appropriate treatment if hypersensitivity reaction occurs.**

**Further information on the safety concern**

Please refer to *section 4.4 "Special warnings and precautions for use"* and *section 4.8 "undesirable effects"* in the Summary of product Characteristics (SPC) for Ultravist for further information on hypersensitivity reaction incidence and manifestations.

**Further information on recommendations to Healthcare**

**Professionals:**

**Precautionary recommendations on hypersensitivity**

- Sensitivity testing using a small test dose of contrast medium is not recommended, as it has no predictive value. Furthermore, sensitivity testing itself has occasionally led to serious and even fatal hypersensitivity reactions.
- Before any contrast medium is injected, the patient should be questioned for a history of allergy (e.g. seafood allergy, hay fever, hives), sensitivity to iodine or to radiographic media and bronchial asthma.
- The reported incidence of adverse reactions to contrast media is higher in patients with above conditions and premedication with glucocorticoids may be considered. However, contrast media and prophylactic agents should not be administered together.
- Hypersensitivity reactions can be aggravated in patients on beta-blockers particularly in the presence of bronchial asthma. Patients who experience such reactions while taking beta blockers may be resistant to treatment effects of beta agonists.



- If hypersensitivity reactions occur, administration of the contrast medium must be discontinued immediately.
- Irrespective of the quantity and type of administration, even mild allergic symptoms may be the first signs of a serious anaphylactoid reaction requiring treatment.
- For this reason, iodinated contrast media should only be employed in medical environments where emergency treatment is available, i.e. the necessary equipment and medications, physicians with sufficient clinical experience, as well as trained assisting medical staff.
- It must therefore be possible to initiate immediate emergency measures for all patients in order to treat a serious reaction, and to maintain direct access to the requisite emergency drugs and emergency surgical kit.
- The patient should be observed for at least ½ hour after the end of administration, as experience shows that the majority of all serious incidents occur within this time period.

**Premedication:**

- It has been common practice to use premedication with corticosteroids either alone or in combination with antihistamines in patients with a history of moderate or severe immediate reaction to contrast media.

**Further information**

Please refer to the Summary of product Characteristics (SPC) for Ultravist for further information specific to each contrast media.

**The information in this letter has been approved by the Saudi Food and Drug Authority.**

**Call for reporting**

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2340.
- Toll free phone: 8002490000
- E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)
- Website: [www.sfd.gov.sa/npc](http://www.sfd.gov.sa/npc)



Or

Pharmacovigilance department in Bayer HealthCare

Bayer HealthCare, Alkamal Office  
Taj Center, 5th Floor, Office 512  
Batha - P.O Box 708, Riyadh 11421  
Kingdom of Saudi Arabia  
Tel.: +966(11) 4141894 (Ext. 500)  
Fax: +966 (11) 4141890  
Email: pv.me@bayer.com

Yours Sincerely,

A handwritten signature in blue ink, appearing to be "Abdullah Rajkhan".

31-Mar-2015

Abdullah Rajkhan  
Pharmacovigilance Country Head, KSA and GCC