

“ Patient Diary for Patient Treated with Anti Epidermal Growth Factor Receptors (Anti EGFRs): Erbix (Cetuximab) ”

**For patients who have been prescribed
Erbix (Cetuximab) as Anti Epidermal
Growth Factor Receptors (Anti EGFRs).**

In order to ensure the safe and effective use of the product and appropriate management of adverse effects, it is advised to be read carefully the insert leaflet before administering the product.

This document has been reviewed and approved by the Food and Drug Authority (SFDA).

MERCK

“I WISH I HAVE A WAY TO KEEP TRACK MY CANCER,,

You couldn't have wished for a more practical and useful tool than the Anti EGFRs Erbitux (Cetuximab) Treatment Diary*. It can easily help you keep track of your Anti EGFRs Erbitux (Cetuximab) injections, as well as the symptoms of your disease. Before you begin, complete the section for important consideration which includes your personal information, emergency contact and medical information.

Anti EGFRs: Anti Epidermal Growth Factor Receptors

*This diary is prepared for patients who have been prescribed Anti EGFRs Erbitux (Cetuximab).





Keeping track of dosage/ injections

Once you begin Anti EGFRs Erbitux (Cetuximab) treatment journey, write down the date and time of your biweekly injections/ the dosing schedule in the diary. Each day has space for you to write down information/ notes about the injection.



Recording symptoms and questions

In your treatment diary, you may want to:



Write down how you are feeling each day. Include details about your overall health, symptoms, and any undesirable effects (such as skin reactions) you might be experiencing with Anti EGFRs Erbitux (Cetuximab).



Write down any questions you want to ask your doctor.



Write down appointments such as doctor visits, upcoming tests/scans, and calls with your treating specialist or nurse.



Review your treatment diary before each of your doctor visits. It's easy to forget the details when you are sitting in a doctor's office. But keeping track of your symptoms and progress can help you and your doctor manage your symptoms.

Remember



Side effects and symptoms vary from one person to another. You should go immediately to the nearest hospital/emergency room if you experience any severe unusual symptom/event or have any urgent inquiry that cannot wait until the following business day.

Note



As with other therapies that treat CRC/mCRC/H&N, Anti EGFRs Erbitux (Cetuximab) can cause undesirable effects. When you start taking Anti EGFRs Erbitux (Cetuximab), you should talk with your doctor about the possible benefits of Anti EGFRs Erbitux (Cetuximab) and its possible side effects to decide how to manage them and improve your Quality of life.

Please see the enclosed Anti EGFRs Erbitux (Cetuximab) Medication Guide and Prescribing Information located in this kit and speak with your doctor for more information.

General information

Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____

Emergency Contact

Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____

Medical information

Doctor's name _____

Doctor's phone _____

Nurse's name _____

Nurse's phone _____

Allergies _____

If you have any questions about your therapy, contact your treating specialist/nurse.

Symptom Tracker

It's important to remember that skin problems are one of the most serious side effects of Anti EGFRs Erbitux (Cetuximab). Skin problems include an acne-like rash, skin drying and cracking, infections, and abnormal hair growth. The skin around your fingernails and toenails may swell. Blistering of the skin or mucous membranes (such as the mouth) or peeling of the skin may be symptoms of serious reactions. You may also experience hair changes and nail changes.¹



Anti EGFRs: Anti Epidermal Growth Factor Receptors

Ref 1. NCCN Task Force Report: Management of Dermatologic and Other Toxicities Associated With EGFR Inhibition in Patients With Cancer. Journal of the National Comprehensive Cancer Network. Vol 7 Supplement 1. 2009 http://www.jco.org/content/7/Suppl_1/S-5-abstract. Boone SL, Rademaker A, Liu D, et al. Impact and management of skin toxicity associated with anti-epidermal growth factor receptor therapy: survey results. Oncology 2007; 72: 152-159. <https://www.ncbi.nlm.nih.gov/pubmed/18160805>. www.fightcancer.org/Resources.



What to look on the front & back of your body?

What to look for on the front of the body?¹⁻³

FACE

Look out for acne-like skin rash. These could be itchy and painful. The rashes may involve a small part of the body (mild rashes) or a large part of the body (severe rashes). These appear about 8-10 days after therapy.

CHEST

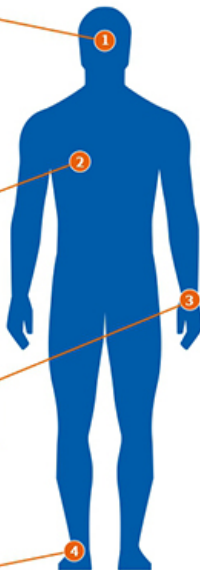
Look for acne-like skin rash. Red, itchy and painful skin rashes can occur on the upper chest, days after therapy, about 8-10 days after therapy.

HANDS

Watch out for painful cracks in the palms and fingertips. This may include drying and scaling skin.

FINGER AND TOE NAILS

Check for any painful swelling (inflammation) filled with pus around the finger and toe nails. This is usually seen in the first digits, and occurs after 2 or more months of therapy. Ridging or cracking of the nails may be seen.



What to look for on the back of the body?¹⁻³

HAIR

You may experience hair changes such as slow hair growth or baldness. Baldness can occur after 2-3 months of therapy. Excessive growth of facial hair & excessive growth with curling of eyelashes occur after 1-2 months therapy. Acne-like skin rash can appear on the scalp too.

BACK

Red, itchy and painful skin rashes can occur on the lower back. You may experience dryness and scaling in these areas.

KNUCKLES

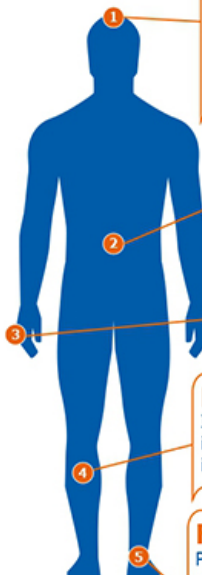
Watch out for painful cracking in the skin over the knuckles.

LIMBS

If have acne-like rashes, you may also develop itchy, dry and scaly skin over the arms and legs in these areas.

FEET

Painful cracks called fissures may appear in the soles and heels. These usually appear around 1-2 months of therapy. There is a chance of infection in these regions.



Ref 1. Pinto C, Barone CA, Girolomoni G et al. Management of Skin Toxicity Associated with Cetuximab Treatment in Combination with Chemotherapy or Radiotherapy. The Oncologist. 2011; 16:228-38. 2. Guidelines for Cetuximab induced rashes. NHS Website. Available at: <http://www.kentmedwaycancernetwork.nhs.uk/search/?q=cetuximab>. Accessed 2 June 2015. 3. Lacouture ME, Anadkat M, Bensadoun RJ et al. Clinical practice guidelines for the prevention and treatment of EGFR inhibitor-associated dermatologic toxicities. Support Care Cancer. 2011; 19:1079-95.

Week 1

Date _____

Symptoms _____



Week 2

Date _____

Symptoms _____



Week 3

Date _____

Symptoms _____



Week 4

Date _____

Symptoms _____



Note: Please see Anti EGFRs insert leaflet available in your medication box and speak with your doctor for more information.

Anti EGFRs: Anti Epidermal Growth Factor Receptors





Other details

You would like to note down or questions to ask your doctor

(for example if you notice skin is having vesicles include pus, or your rash is getting more tender/scaly, or you noticed changes in bowel habits)



Notes

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Kindly report any suspected adverse reactions associated with the use of your medication to the SFDA and to the MOH.

The National Pharmacovigilance Centre (NPC), Saudi Food and Drug Authority (SFDA)

SFDA call center: 19999

Fax: +966 11 2057662

E-mail: npc.drug@sfda.gov.sa

Website: <http://ade.sfda.gov.sa>

Anti EGFRs: Anti Epidermal Growth Factor Receptors

CRC: Colorectal cancer

mCRC: Metastatic colorectal cancer

LS mCRC: Left side metastatic colorectal cancer

QoL: Quality of life

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SA-ERB-00007