Penicillin G Benzathine

For Injectable Suspension

2.4 MIU

This package insert is continually updated: please read carefully before using a new pack. In case of any question, please contact your physician or pharmacist.

IDENTIFICATION OF THE MEDICINAL PRODUCT

Composition

Each vial contains :

Penicillin G Benzathine USP

eq. to Penicillin 2,400,000 IU.

PHARMACEUTICAL FORM

Powder for suspension for injection (IM).

PHARMACO-THERAPEUTIC CLASS

Antibiotics belonging to the penicillin family (I: anti-infective agent).

WHEN SHOULD THIS DRUG BE USED

(Therapeutic indications)

This drug is indicated in the prophylaxis and the treatment of certain bacterial infections due to sensitive germs, in particular:

- Prophylaxis of relapses of rheumatic fever,
- Treatment of syphilis and yaws.

ATTENTION !

WHEN SHOULD THIS DRUG NOT BE USED

(Contraindications)

This drug must not be used in the following situation:

Know allergy to antibiotics belonging to the beta-lactam family (penicillins and cephalosporins). Indeed, cross allergy risk with antibiotics belonging to the cephalosporin family must be taken into account.

In case of doubt you should consult your physician or pharmacist.

WARNINGS AND PRECAUTIONS

Warnings

+ Any allergic manifestation (skin rashes, itching) occurring during the treatment must be immediately notified to your physician.

+ Before taking this drug inform your physician in case of history of allergic reaction to penicillins or cephalosporins during a previous antibiotic therapy: Urticaria or other skin rashes, itching, angioedema (see Undesirable effects). In case that a similar reaction has already happened, this drug is strictly contraindicated.

+ If diarrhea occurs, it could be exceptionally symptomatic of pseudo-membranous colitis (see Undesirable effects). Consult immediately your physician.

PRECAUTION

Inform your physician in case of :

- Renal insufficiency,
- History of allergy, especially to antibiotics.

In case of low or without salt diet, beware or the sodium intake:

- Extencimon 2.4 MIU : 22mg per vial.

In case of doubt do not hesitate to consult your physician or pharmacist.

INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

In order to avoid possible interactions with other drugs, and in particular with or anticoagulants, *you must inform your physician or pharmacist about any other current treatment.*

PREGNANCY AND LACTATION

This drug can be used during pregnancy if needed.

Breastfeeding is possible with the use of this drug. Nevertheless, if the newborn shows troubles such as diarrhea, skin rashes, candidiasis (see Undesirable effects), inform immediately your physician for advice because these effects may be related to this drug.

As a general rule, you should always ask the advice of your physician or pharmacist before taking any medicine during pregnancy or lactation.

HOW SHOULD THIS DRUG BE USED

In all cases, strictly follow the physician's prescription.

Dosage

+ Prophylaxis of relapses of rheumatic fever. One intramuscular- injection (IM) every 15 days of:
- 2.4 MIU in adult,
- 0.6 MIU to 1.2 MIU in child, according to the age.
+ Syphilis and yaws treatment: one intramuscular injection (IM) of 2.4 MIU every 8 days.

Method of administration

Prepare aseptically the injectable suspension by injecting into the vial:
- Dissolve the contents of the vial in 5 ml of Sterile Water for Injection.

Shake carefully before use.

FOR DEEP INTRAMUSCULAR INJECTION ONLY.Do not inject intravenously

UNDESIRABLE EFFECTS

Like only active product, this drug may induce, in some patients, undesirable effects to a greater or lesser degree.

+ Gastrointestinal disorders: Nausea, vomiting, diarrhea, candidiasis (infection due to certain white microscopic fungi).
+ Allergic reactions, such as urticaria (skin eruptions with itching wheals), eosinophilia (increase the number of certain white blood cells), angioedema (reaction characterized by swelling of face, tongue, throat or larynx), difficulty in breathing exceptionally anaphylactic shock (a severe allergic reaction of sudden onset).
+ Rashes caused by allergy or not.
+ More rarely, other immunoallergic reactions can be observed.
- Possible modifications of blood cells count such as: Anemia, leucopenia (insufficient amount of white blood cells), thrombopenia (abnormal low rate of platelets) which can lead to nose or gums bleeding, unexplained fever, pallor or intense tiredness. You must rapidly inform your physician,
- Serous kidney disease (acute interstitial nephritis),
- Mild and transient increase of certain liver enzymes (transaminases).
+ Some cases of pseudo-membranous colitis have been reported (inflammation of the intestine with pain and diarrhea).
+ Administration of high doses of beta-lactam antibiotic, particularly in patients suffering from renal insufficiency, can lead to encephalopathy (consciousness disorders, abnormal movements, convulsions).

Do not hesitate to ask your physician or pharmacist for advice and to report any undesirable effect not mentioned in this leaflet.

EXPIRY DATE

Do not use later than the date of expiry indicated on the outer packaging.

STORAGE

Store between temperature 8° to 25°C. Protect from moisture.
Keep out of the reach of children.

PRESENTATION

Each vial packed in a printed carton.

Manufactured by:
Kwality Pharmaceuticals Ltd.
Nag Kalan, Majitha Road,
Amritsar - India