

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Benzathine Benzylpenicillin 1,2 & 2,4 MU Ando, Powder for Suspension – Injection

Benzathine Benzylpenicillin 1,2 & 2,4 MU Ando, Powder for Suspension – Injection

Benzathine bezympenicillin

Sugar free

Read all of this leaflet carefully before you are given Benzathine Benzylpenicillin Ando

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Benzathine Benzylpenicillin Ando is and what it is used for
2. What you need to know before you use Benzathine Benzylpenicillin Ando
3. How to use Benzathine Benzylpenicillin Ando
4. Possible side effects
5. How to store Benzathine Benzylpenicillin Ando
6. Contents of the pack and other information

1. What Benzathine Benzylpenicillin Ando is and what it is used for

This medicine contains benzylpenicillin benzathine, which is one of a group of medicines known as penicillins (“antibiotics”). Antibiotics are used to kill the bacteria (germs) which cause infections.

Benzathine Benzylpenicillin Ando is used for the treatment of:

- Streptococcal pharyngitis (sore throat);
- Syphilis of less than 1 year duration;

- Uncomplicated cases of erysipeloid (an infection of the upper or outer skin and underlying layers);
- Prophylactic (preventative) use: recurrence of rheumatic fever.

2. What you need to know before you use Benzathine Benzylpenicillin Ando

Benzathine Benzylpenicillin Ando should not be administered to you if:

- You have a hypersensitivity (allergic) reaction to **penicillin or cephalosporins** or any of the other ingredients of Benzathine Benzylpenicillin Ando (listed in section 6).
- Benzathine Benzylpenicillin Ando must not be given to babies, born to mothers who are allergic to penicillin during the neonatal period.
- You have an inflammation of the inner layer of the heart (endocarditis), inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs (peritonitis), an acute inflammation of the protective membranes covering the brain and spinal cord (meningitis).

Benzathine Benzylpenicillin Ando should not be injected into any of your veins.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with Benzathine Benzylpenicillin Ando:

- you have ever had an allergic reaction to other antibiotics like penicillin or other beta-lactam antibiotics;
- you have kidney problems (your doctor may need to adapt the dose of this medicine);
- you have liver problems.

If allergic symptoms occur (e.g., skin rash, itching, shortness of breath), tell a doctor immediately. Before treatment, a hypersensitivity test should be performed if possible. If an allergic reaction occurs, your doctor will stop your treatment and, if necessary, start appropriate therapy.

As a possible cross-allergy should be considered in patients with hypersensitivity to cephalosporins, please tell your doctor if you have already had a previous allergic reaction to certain antibiotics (cephalosporins).

If you have already been diagnosed with an allergy and/or allergic asthma or hay fever, you should tell your doctor. Severe immediate allergic reactions are possible even when the drug is administered for the first time. Based on general principles, in some cases you will remain under observation for at least half an hour after the medicine has been administered in case an acute allergic reaction should occur. If an allergy occurs, the doctor will take appropriate measures. Treatment with benzylpenicillin benzathine must be stopped immediately.

When treating syphilis, a reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 4). Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness. To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.

In long-term treatment (more than a single dose), your doctor may arrange for checks on your blood count and liver and kidney function tests. Please make sure that you attend the check-ups prescribed by the doctor.

Other medicines and Benzathine Benzylpenicillin Ando

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Caution should be exercised when administering benzylpenicillin benzathine at the same time as the following medicines:

- probenecid, a medicine used to treat gout.
- methotrexate, a medicine used in chemotherapy. The combination with methotrexate is not recommended.
- anticoagulants: medicines used to thin the blood.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Benzathine Benzylpenicillin Ando.

Do not receive Benzathine Benzylpenicillin Ando if you are pregnant or breastfeeding your baby.

Driving and using machines

Benzathine Benzylpenicillin Ando can impair responsiveness and the ability to drive. Due to the occurrence of possible serious side effects (e.g. anaphylactic shock with collapse and allergic-like reactions (e.g. stomach upsets), see section 4), Benzathine Benzylpenicillin Ando can have a major influence on the ability to drive and use machines.

It is not always possible to predict to what extent Benzathine Benzylpenicillin Ando may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machinery until you are aware of the measure to which Benzathine Benzylpenicillin Ando affects you.

Benzathine Benzylpenicillin Ando contains phospholipids from the soya lecithin.

This medicine contains phospholipids from soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

3. How to use Benzathine Benzylpenicillin Ando

You will not be expected to give yourself Benzathine Benzylpenicillin Ando. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with Benzathine Benzylpenicillin Ando will last.

If you have the impression that the effect of Benzathine Benzylpenicillin Ando is too strong or too weak, tell your doctor or pharmacist.

Benzathine Benzylpenicillin Ando is for **INTRAMUSCULAR USE ONLY**.

You will be administered Benzathine Benzylpenicillin Ando by deep injection into a muscle once a month.

Benzathine Benzylpenicillin Ando must NEVER be injected into your veins.

If you receive more Benzathine Benzylpenicillin Ando than you should

Since a healthcare provider will administer Benzathine Benzylpenicillin Ando, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Benzathine Benzylpenicillin Ando

Since a healthcare provider will administer Benzathine Benzylpenicillin Ando, it is unlikely that the dose will be missed.

4. Possible Side Effects

Benzathine Benzylpenicillin Ando can have side effects.

Not all side effects reported for Benzathine Benzylpenicillin Ando are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Benzathine Benzylpenicillin Ando, please consult your healthcare provider for advice.

If any of the following happens, stop using Benzathine Benzylpenicillin Ando and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Benzathine Benzylpenicillin Ando. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- allergic reactions which may include exfoliative dermatitis (peeling of the skin over large areas of the body), other skin rashes

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- fungal infection (candidiasis)
- diarrhoea
- nausea
- inflammation of the lining of the mouth (stomatitis) and of the tongue (glossitis)
- being sick (vomiting)
- changes in certain test and investigation results performed by your doctor
- kidney inflammation (interstitial nephritis)
- inflammation of the blood vessels

Less frequent side effects

- certain blood disorders (so called leukopenia, thrombocytopenia, agranulocytosis)
- prolongation of bleeding time, defective platelet function
- allergic reactions including hives, swelling, skin reactions, fever, painful joints, anaphylactic shock with collapse and asthma, skin bleeding (purpura) and gastrointestinal complaints (anaphylactoid reactions)
- sore mouth or tongue and black, hairy tongue
- kidney disease (nephropathy)

Side effects with unknown frequency

- a blood disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia)
- an abnormally low count of a type of white blood cell (neutrophils), defective blood platelet function which can prolong bleeding time
- serum sickness (when antigens (substances that trigger an immune response) in certain medications and antiserums cause your immune system to react)
- antibiotic-associated diarrhoea caused by inflammation of the colon (Pseudomembranous colitis)
- heartburn
- liver inflammation (hepatitis)
- impairment of bile flow (cholestasis)
- increases in liver enzymes
- pain at the injection site
- injection site infiltrates
- penicillin psychosis (Hoigné and Nicolau Syndrome)

When treating syphilis, a reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 2). Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness. To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Benzathine Benzylpenicillin Ando.

5. How to store Benzathine Benzylpenicillin Ando

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Benzathine Benzylpenicillin Ando should not be administered after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- Any Benzathine Benzylpenicillin Ando which is left over, not used or has passed its expiry date will be disposed of by hospital staff.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets)

6. Contents of the pack and other information

The active substance is benzathine benzylpenicillin.

Benzathine Benzylpenicillin Ando 1,2 MU: benzathine benzylpenicillin 989 mg equivalent to benzylpenicillin 1,2 mega.

Benzathine Benzylpenicillin Ando 2,4 MU: benzathine benzylpenicillin 1977,7 mg equivalent to benzylpenicillin 2,4 mega.

The other ingredient is lecithin.

What Benzathine Benzylpenicillin Ando looks like and contents of the pack

Dry: White to almost white powder.

Holder of Certificate of Registration

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BENZATHINE BENZYL PENICILLIN 2.4 MU ANDO: 56/20.1.2/0385