

1.3.2.1 Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AUGSPEC POWDER FOR ORAL SUSPENSION POWDER FOR ORAL

SUSPENSION

Amoxicillin and clavulanic acid

Contains sweetener:

Acesulfame Potassium: 9,6 mg / 5 ml

Saccharin Sodium: 4,8 mg / 5 ml

Read all of this leaflet carefully before you start taking AUGSPEC POWDER

FOR ORAL SUSPENSION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AUGSPEC POWDER FOR ORAL SUSPENSION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AUGSPEC POWDER FOR ORAL SUSPENSION is and what it is used for
2. What you need to know before you take AUGSPEC POWDER FOR ORAL SUSPENSION
3. How to take AUGSPEC POWDER FOR ORAL SUSPENSION

4. Possible side effects
5. How to store AUGSPEC POWDER FOR ORAL SUSPENSION
6. Contents of the pack and other information

1. What AUGSPEC POWDER FOR ORAL SUSPENSION is and what it is used for

AUGSPEC POWDER FOR ORAL SUSPENSION contains two active ingredients called amoxicillin and clavulanic acid. This belongs to a group of medicines called penicillins.

AUGSPEC POWDER FOR ORAL SUSPENSION is used to treat bacterial infections in children.

2. What you need to know before you take AUGSPEC POWDER FOR ORAL SUSPENSION

Do not take AUGSPEC POWDER FOR ORAL SUSPENSION

- If you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine (listed in section 6);
- If you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck;
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Warnings and precautions

Take special care with AUGSPEC POWDER FOR ORAL SUSPENSION:

- If you develop a skin rash while taking AUGSPEC POWDER FOR ORAL SUSPENSION, stop AUGSPEC POWDER FOR ORAL SUSPENSION at

once and notify your doctor;

- If you develop frequent and persistent diarrhoea and stomach cramps and notify your doctor;
- If you have glandular fever;
- If you are being treated for liver or kidney problems;
- If you are not passing water regularly;
- If you are taking medication known as anticoagulants (blood thinners);
- If you are being treated for lymphatic leukaemia (a type of cancer that affects white blood cells);
- If you are having any blood tests done, tell you doctor that you are taking

AUGSPEC POWDER FOR ORAL SUSPENSION.

Other medicines and AUGSPEC POWDER FOR ORAL SUSPENSION

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

(This includes all complementary or traditional medicines).

Please inform your healthcare professional if you are currently taking any of the following medicines:

- If you are taking allopurinol (used for gout) with your medicine, it may be more likely that you'll have an allergic skin reaction;
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of your medicine;
- If medicines to help stop blood clots (such as warfarin) are taken with your medicine, then extra blood tests may be needed;
- Your medicine can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works;
- If you are taking medicine containing alcohol, as it may cause a disulfiram-like reaction, which includes symptoms such as nausea,

vomiting, flushing, dizziness, throbbing headache, chest and abdominal discomfort, and general hangover-like symptoms;

- If you are taking oral contraceptives ('the pill'), AUGSPEC POWDER FOR ORAL SUSPENSION may cause it work less effectively;
- Your medicine can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

AUGSPEC POWDER FOR ORAL SUSPENSION with food and/or drink

AUGSPEC POWDER FOR ORAL SUSPENSION should be taken at the start of a meal.

Alcohol should be avoided during and for several days after treatment with AUGSPEC POWDER FOR ORAL SUSPENSION (see disulfiram-like reaction above).

Pregnancy and breastfeeding

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 health care provider for advice before taking AUGSPEC POWDER FOR ORAL SUSPENSION.

You should not take AUGSPEC POWDER FOR ORAL SUSPENSION if you are pregnant or breastfeeding your baby.

Driving and using machines

AUGSPEC POWDER FOR ORAL SUSPENSION may affect your ability to drive or operate machines and caution is advised until the effects of AUGSPEC POWDER FOR ORAL SUSPENSION on treatment are known.

It is not always possible to predict to what extent AUGSPEC POWDER FOR ORAL SUSPENSION may interfere with your daily activities. You should ensure that you

do not engage in the above activities until you are aware of the measure to which AUGSPEC POWDER FOR ORAL SUSPENSION affects you.

3. How to take AUGSPEC POWDER FOR ORAL SUSPENSION

Do not share medicines prescribed for you with any other person. Always take AUGSPEC POWDER FOR ORAL SUSPENSION exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will advise you how much of AUGSPEC POWDER FOR ORAL SUSPENSION you should take depending on your body weight and condition.

Always shake the bottle well before use.

Take AUGSPEC POWDER FOR ORAL SUSPENSION at the start of a meal.

Space the doses evenly during the day.

Keep taking the medicine until the course is completed. Do not stop, even if you feel better.

Your doctor will tell you how long your treatment with AUGSPEC POWDER FOR ORAL SUSPENSION will last. If you have the impression that the effect of AUGSPEC POWDER FOR ORAL SUSPENSION is too strong or too weak, tell your doctor or pharmacist.

If you take more AUGSPEC POWDER FOR ORAL SUSPENSION than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take AUGSPEC POWDER FOR ORAL SUSPENSION

Take it as soon as you remember and continue as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking AUGSPEC POWDER FOR ORAL SUSPENSION

Your doctor will decide you how long your treatment with AUGSPEC POWDER FOR ORAL SUSPENSION will last. Do not stop your treatment with AUGSPEC POWDER FOR ORAL SUSPENSION without consulting your doctor first.

4. Possible side effects

AUGSPEC POWDER FOR ORAL SUSPENSION can have side effects.

Not all side effects reported for AUGSPEC POWDER FOR ORAL SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AUGSPEC POWDER FOR ORAL SUSPENSION, please inform your health care provider for advice.

If any of the following happens, stop taking AUGSPEC POWDER FOR ORAL SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, 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 AUGSPEC POWDER FOR ORAL SUSPENSION. You may need urgent medical attention.

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

- Jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow. This may indicate a problem with your liver.
- Inflammation of tubes in the kidney which may cause fever, blood in the urine, change in urine output.
- Blood takes longer to clot.
- Convulsions (in people taking high doses of this medicine or who have kidney problems).
- Severe reduction in the number of white blood cells, which may cause fever, chills, sore throat and other signs of infection.
- Low number of red blood cells (haemolytic anaemia) which may cause abnormal paleness, yellowish skin, eyes, and mouth (jaundice), dark-coloured urine, fever or weakness.
- Pain, fever and cloudy or foamy urine.
- Severe diarrhoea (maybe with blood or mucus) which may be accompanied by stomach cramps.
- Fever, rash, facial swelling, enlarged lymph nodes indicating a severe reaction to AUGSPEC POWDER FOR ORAL SUSPENSION
- Skin rash, itching, skin rash which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - erythema multiforme).

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

Tell your doctor or health care provider if you notice any of the following:

Frequent side effects:

- Diarrhoea, headache, fever, and chills.
- Thrush (candida – a yeast infection of the vagina, mouth, or skin folds).
- Feeling sick (nausea), especially when taking high doses if affected take your medicine before food.
- Vomiting.

Less frequent side effects:

- Raised itchy rash (hives).
- Indigestion.
- Hyperactivity.
- Dizziness.
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
- Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Stained teeth (in children), usually removed by brushing.
- Black tongue which looks hairy.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AUGSPEC POWDER FOR ORAL SUSPENSION.

5. How to store AUGSPEC POWDER FOR ORAL SUSPENSION

Store the powder for oral suspension at or below 25 °C

Store the reconstituted suspension in a refrigerator (2 – 8 °C) and use within 10 days.

Keep the container in the outer carton until required for use.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What AUGSPEC POWDER FOR ORAL SUSPENSION contains

- Each 5 mL suspension contains amoxicillin trihydrate equivalent to 600 mg amoxicillin and potassium clavulanate equivalent to 42,9 mg clavulanic acid
- The other ingredients are acesulfam potassium, carmellose sodium, crospovidone Type A, saccharin sodium, silica colloidal anhydrous, silicon dioxide, strawberry flavour (flavouring components, maize maltodextrin, propylene glycol, triethyl citrate), xanthan gum.

What AUGSPEC POWDER FOR ORAL SUSPENSION looks like

AUGSPEC POWDER FOR ORAL SUSPENSION is a white to yellowish powder.
After reconstitution it is a white to yellowish coloured suspension with strawberry
flavour

AUGSPEC POWDER FOR ORAL SUSPENSION is filled into an amber glass
type III bottle with a nominal volume of 60 mL (for 30 mL oral suspension), 100
mL (for 50 mL or 70 mL oral suspension) or 150 mL (for 100 mL oral
suspension), closed with a PP white screw cap containing a liner. The liner can
be of ALU or desiccant. The bottles are packed in a cardboard carton with a
dosing device (6 mL PE/PS syringe, 5 mL or 10 mL PS spoon or a 5 mL PP cup).
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.trinitypharma.co.za