PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Moxypen® Forte 250 mg Powder for Suspension

Composition:
Each 5 ml contain:
Amoxicillin (as trihydrate) 250 mg
For information on the inactive and allergenic ingredients, see section 2 – "Important information on some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is intended for the treatment of infections caused by bacteria susceptible to amoxicillin. In addition, it is intended for the prevention of bacterial infections in patients who are at risk for developing bacterial endocarditis.

Therapeutic group
Antibiotic of the penicillins group.
There are infections caused by viruses, such as the common cold. Moxypen Forte 250 mg Powder for Suspension does not affect viruses.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine.
- You are sensitive to the packaging components of the medicine.
- You are sensitive to other medicines from the penicillin or cephalosporin group or to similar antibiotics such as amoxicillin, ampicillin, cephalexin and others.
- You are suffering from mononucleosis (either suspected or confirmed).

Special warnings regarding use of the medicine
Before treatment with Moxypen Forte 250 mg Powder for Suspension, tell the doctor if:
- You have suffered in the past from an allergic reaction to beta-lactam antibiotics (such as ampicillin, piperacillin). See section 4 – "Side Effects".
- You are taking blood thinning medicines (such as warfarin, etc.).
- You have suffered in the past from diarrhea or inflammation of the large intestine (colitis) as a result of the use of antibiotics.
- You are suffering from kidney problems.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- Medicines to treat cancer (such as methotrexate)
- Medicines for heartburn or gout (probenecid or cimetidine)
- Blood thinner medicines (such as warfarin) – may cause bleeding
- Oral contraceptives – amoxicillin may reduce the effectiveness of the pills
- Antibiotics (such as tetracyclines) – may reduce the effectiveness of amoxicillin

Use of the medicine and food
Take the medicine between meals with a glass of water.

Pregnancy and breastfeeding
If you are pregnant or are planning to become pregnant, consult the doctor before taking the medicine.
If you are breastfeeding or planning to breastfeed, consult with your doctor about how to breastfeed while using this medicine.

Important information about some of the ingredients of the medicine
- This medicine contains less than 23 mg of sodium per 5 ml spoonful and therefore is considered sodium-free.
- This medicine contains sucrose (about 3 grams per 5 ml of suspension). If you have been told by the doctor that you have an intolerance (sensitivity) to certain sugars, consult the doctor before taking the medicine.
- The medicine contains a red coloring agent, FD&C red #40 (E129), which may cause allergic reactions.
- This medicine contains sodium benzoate (E211) (2.79 mg in 5 ml suspension). Sodium benzoate can increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks of age).
- This medicine contains benzyl alcohol (about 1.5 mg in 5 ml suspension) which may cause allergic reactions. Benzyl alcohol is suspected to be a risk factor for serious side effects including breathing problems in young children. Do not administer to newborn babies (up to 4 weeks old), unless recommended by the doctor. Do not use for more than a week in young children (under 3 years old), unless recommended by the doctor, due to an increased risk of the substance accumulating in their body.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
The attending doctor will determine the required dose of the medicine and the length of time the medicine should be taken, depending on the type and severity of the infection you or your child have. Tell the doctor if the condition does not improve.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally:
Infection of the upper respiratory tract, lungs, skin or soft tissues:
Adults and children above 10 years of age: 250-500 mg, 3 times a day, every 8 hours.
Children 2-10 years of age: 125 mg, 3 times a day, every 8 hours. In severe infections the dosage may be increased to 250 mg, 3 times a day.
Infants under 2 years of age: 62.5 mg, 3 times a day, every 8 hours.
The recommended dose according to body weight is 20 mg/kg per day, in divided doses every 8 hours. In severe infections, the dose can be increased to 40 mg/kg per day, in divided doses every 8 hours.
Uncomplicated urinary tract infection or gonorrhea:
Adults: 3 grams as a single dose.
Children: 100 mg/kg as a single dose.
Prophylaxis for bacterial endocarditis (in dental treatment):
Adults and children above 10 years of age: 3 grams as a single dose, one hour before starting treatment.
Children below 10 years of age: 1.5 grams as a single dose, one hour before starting treatment.

Be sure to measure the suspension dose using the measuring spoon.
Take the medicine between meals with a glass of water.
Do not exceed the recommended dose.

Directions for preparation of the medicine
Prepare the suspension according to the preparation instructions that appear on the bottle label: tap the bottle to loosen the powder.
To a bottle containing powder for preparation of 60 ml: add 36 ml of distilled water.
To a bottle containing powder for preparation of 100 ml: add 60 ml of distilled water.
Shake the bottle well before each use.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you, even if you do not experience symptoms. Symptoms of an overdose may include: severe dizziness.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember. If you remember close to the time of the next dose, skip the forgotten dose and continue treatment as usual. Never take two doses together to compensate for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine
Even if the symptoms have disappeared, it is important to complete the treatment as recommended by the doctor. Early discontinuation of the treatment, misuse or overuse may lead to development of bacterial resistance to the medicine and to recurrence of the infection.
This means that the medicine may not benefit you in the future.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Moxypen Forte 250 mg Powder for Suspension may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to the doctor immediately in the following cases:
Common side effects (effects occurring in 1-10 users out of 100):
Rash; cracked skin or other effects on skin and eyes; nausea; vomiting; diarrhea; bloody stools

Uncommon side effects (effects occurring in 1-10 users out of 1,000):
Anaphylaxis (severe allergic reactions such as swelling in the nose, eyes, throat, breathing difficulties, skin blistering, rash and skin peeling); symptoms of kidney problems (such as cloudy urine); symptoms of liver problems (such as persistent nausea and vomiting, abdominal pain, unusual tiredness, yellowing of the eyes or skin, dark urine)

Rare side effects (effects occurring in 1-10 users out of 10,000):
Severe skin reaction (flu-like symptoms, blistering and peeling of the skin); severe cutaneous adverse reactions (SCAR), severe skin reactions that may also affect other organs:
- Skin peeling, scaling or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin discoloration (redness, yellowing or purpling)
- Swelling and redness of the eyes or face
- Flu-like feeling, fever, chills, body aches, swollen lymph glands, cough
- Shortness of breath, chest pain or discomfort

Consult the doctor if the following side effects occur:
Common side effects (effects occurring in 1-10 users out of 100):
Black tongue that appears hairy (glossitis); teeth discoloration in children (brown, yellow or gray staining); dizziness; anxiety

Uncommon side effects (effects occurring in 1-10 users out of 1,000):
Skin allergy (hives), itch; rash on the face; swelling

Rare side effects (effects occurring in 1-10 users out of 10,000):
Difficulty in falling asleep (insomnia); confusion or changes in behavior; changes in blood test results

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- **Dry powder: Store the powder in a dry place, below 25°C.**
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Prepared suspension: Keep in the refrigerator or at room temperature and use within 14 days.**
- Do not discard medicines into the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sucrose, spray dried artificial flavor (cherry raspberry type), silicon dioxide, sodium citrate anhydrous, xanthan gum, sodium benzoate, FD&C red # 40.

What the medicine looks like and the contents of the package
A bottle containing an off white to pinkish powder. After adding water, a pink-colored liquid will be obtained.
There are 2 package sizes: a package containing powder for preparation of 60 ml suspension, a package containing powder for preparation of 100 ml suspension
Not all package sizes may be marketed.

Name of License Holder and its Address
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Name of Manufacturer and its Address
Teva Canada Ltd., Toronto, Ontario, Canada.

This leaflet was revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
132.01.31050

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