PATIENT LEAFLET 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 contains: amoxicillin (as trihydrate) 250 mg

For information regarding inactive ingredients and allergens, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. 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 THE MEDICINE INTENDED FOR?

The medicine is intended for treatment of infections caused by bacteria sensitive to amoxicillin. In addition, the medicine is intended to prevent bacterial infection in patients at risk of developing bacterial endocarditis.

Therapeutic class

Penicillin antibiotic.

Some infections are caused by viruses, such as the common cold. Moxypen Forte 250 mg Powder for Suspension does not harm viruses.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains.
- You are sensitive to the components of the package of the medicine.
- You have a sensitivity to other medicines from the penicillin or cephalosporin group or to a similar antibiotic such as amoxicillin, ampicillin, cefalexin and others.
- You have or are suspected to have infectious mononucleosis.

Special warnings regarding the 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 an antibiotic from the beta-lactam group (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 colon (colitis) as a result of using antibiotics.
- You have 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 the pharmacist. Especially if you are taking:

- Medicines to treat cancer (such as methotrexate)
- Medicines for heartburn or gout (probenecid or cimetidine)
- Blood thinning medicines (such as warfarin) – may cause bleeding
- Contraceptive pills – amoxicillin may decrease the effectiveness of the contraceptive pills
- Antibiotics (such as tetracyclines) – may decrease the effectiveness of amoxicillin

Moxypen may affect the results of lab tests. Consult your doctor if needed.

Use of the medicine and food

The medicine should be taken between meals with a glass of water.

Pregnancy and breastfeeding

If you are pregnant or planning to become pregnant, consult the doctor before taking the medicine.

If you are breastfeeding or planning to breastfeed, consult the doctor regarding how to breastfeed while using the medicine.

Important information about some of the ingredients of the medicine

- This medicine contains less than 23 mg of sodium per spoon (5 ml), and is therefore considered sodium-free.
- This medicine contains sucrose (about 3 grams in 5 ml suspension). If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.
- The medicine contains 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 may increase jaundice (yellowing of the skin and eyes) in newborns (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 severe side effects, including breathing problems in young children. Do not use in newborns (up to 4 weeks of age) unless recommended by the doctor. Do not use for more than one week in young children (under 3 years of age), unless recommended by the doctor, due to the increased risk of accumulation of the substance 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 about the dosage and how to use the preparation.

The treating doctor will determine the required dosage of the medicine and the length of time the medicine should be taken according to the type and severity of the infection you or your child suffer from. Tell the doctor if there is no improvement in your condition.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Infection in the upper respiratory tract, lungs, skin or soft tissues:

Adults and children over the age of 10 years: 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 dose can be increased to 250 mg, 3 times a day.

Infants under two years of age: 62.5 mg, 3 times a day, every 8 hours.

The recommended dosage according to body weight is 20 mg/kg per day, divided into one dose every 8 hours. In severe infections, the dosage can be increased to 40 mg/kg per day, divided into one dose every 8 hours.

Uncomplicated urinary tract infection or gonorrhea:

Adults: 3 grams in a single administration.

Children: 100 mg/kg in a single administration.

Prophylaxis for bacterial endocarditis (in dental treatments):

Adults and children over the age of 10 years: 3 grams in a single administration, one hour before starting treatment.

Children below 10 years of age: 1.5 grams in a single administration, one hour before starting treatment.

Make sure to measure the dose of the suspension with the measuring spoon. The medicine should be taken between meals with a glass of water.

Do not exceed the recommended dose.

How to prepare 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 take the package of the medicine with you, even if you do not feel symptoms. Symptoms of an overdose may include: severe dizziness.

If you forgot to take this medicine at the appointed time, take your dose as soon as you remember. If you remember close to the time of the next dose, skip the missed dose and continue treatment as usual. Do not take two doses together to compensate for the forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

Even if the symptoms have passed, it is important to complete the treatment as recommended by the doctor. Discontinuing the treatment before time, misuse or overuse may lead to the 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 every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using 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 experience any of them.

Stop the treatment and refer to a doctor immediately in the following cases:

Common side effects (effects that occur in 1-10 users out of 100):

Rash; skin cracking or other effects on the skin and eyes; nausea; vomiting; diarrhea; bloody stool.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

Anaphylaxis (acute allergic reaction such as swelling of the nose, eyes, throat, breathing difficulties, blisters on the skin, rash and skin peeling); symptoms of kidney problems (such as cloudy urine); symptoms of liver problems (such as repeated nausea and vomiting, abdominal pain, unusual tiredness, yellowing of the eyes or skin, dark urine).

Rare side effects (effects that occur in 1-10 users out of 10,000):

Acute skin reaction (flu-like symptoms, blisters and peeling of the skin); severe cutaneous adverse reactions (SCAR), severe skin reactions that may also affect other organs:

- Peeling, scaling or blisters on the skin (with or without pus) which may also affect the eyes, mouth, nose or genitals, itch, severe rash, lumps under the skin, skin pain, skin discoloration (redness, yellowing or a purple color)
- Swelling and redness of the eyes or face
- A flu-like feeling, fever, chills, body aches, swollen lymph nodes, cough
- Shortness of breath, pain or discomfort in the chest

Side effects with unknown frequency:

Aseptic meningitis (not caused by bacteria): confusion, fever, nausea, tiredness, sudden headaches or stiffness of the neck, sensitivity to light, vomiting.

Consult a doctor if the following side effects occur:

Common side effects (effects that occur in 1-10 users out of 100):

Black tongue that appears hairy (inflammation of the tongue); teeth discoloration in children (brown, yellow or gray stains); dizziness; anxiety.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

Skin allergy (hives), itch; facial rash; swelling.

Rare side effects (effects that occur in 1-10 users out of 10,000):

Difficulty falling asleep (insomnia); confusion or behavioral changes; changes in the results of blood tests.

Side effects observed post-marketing:

Kounis syndrome – a severe allergic reaction that may cause a myocardial infarction (heart attack), it may appear as chest pain in case of an allergic reaction to amoxicillin.

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- **Dry powder: store the powder in a dry place under 25°C.**
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Prepared suspension: store in a refrigerator or at room temperature and use within 14 days.**
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. ADDITIONAL 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 does the medicine look like and what are the contents of the package?

A bottle that contains a cream-light pink powder. After adding the water, a pink-colored liquid will be obtained.

There are 2 package sizes: a package that contains powder for preparation of 60 ml suspension, a package that contains powder for preparation of 100 ml suspension.

Not all package sizes may be marketed.

Name and address of the license holder

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Name and address of the manufacturer

Teva Canada Ltd., Toronto, Ontario, Canada.

The leaflet was revised in August 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 132.01.31050

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