

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

The medicine is dispensed with a doctor's prescription only

Moxypen® Forte 500 mg Capsules

Composition:

Each capsule contains: amoxicillin (as trihydrate) 500 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.

Some people who have taken penicillin antibiotics such as Moxypen Forte (amoxicillin) have developed serious allergic reactions, including a severe skin reaction and death. If you have had an allergic reaction to penicillin antibiotics, cephalosporins or other allergens in the past, you should inform the treating doctor before starting treatment with Moxypen Forte.

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 500 mg Capsules does not harm 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 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 500 mg Capsules, 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 pills
- Antibiotics (such as tetracyclines) – may decrease the effectiveness of amoxicillin

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 capsule, and is therefore considered sodium-free.

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 suffer from. Tell the doctor if there is no improvement in the 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.

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 gonorrhoea:

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.

Moxypen Forte 500 mg oral capsules are not usually intended for children and infants under 6 years of age.

For patients who cannot swallow or require treatment with doses lower than 500 mg, there are suitable registered preparations available in Israel (such as suspension).

Do not exceed the recommended dose.

Instructions for opening the blister: separate one capsule along the perforation mark on the tray and pull the blister paper in the direction of the arrow.

How to use the medicine: swallow the capsule whole with a glass of water, between meals.

No information is available regarding opening the capsule and dispersing its content.

Tell the doctor if your condition is not improving.

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 a 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 500 mg Capsules 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.

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

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

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

- Anaphylaxis (acute allergic reaction): swelling of the nose, eyes, throat, breathing difficulties, blisters on the skin, lumpy rash and skin peeling, fainting.
- Angioneurotic edema: painful swelling of the face, eyes, lips, tongue and/or throat, of the hands or legs; itchy skin rash, skin redness, hives, abdominal pain, dizziness and difficulty breathing.
- Erythema multiforme (serious skin reaction): a skin rash which may appear as target-like blisters (circular spots with a dark center, surrounded by a lighter area with a dark ring around it).
- Kidney problems: cloudy urine, blood in the urine which may be accompanied by rash, fever, joint pain; or decreased urination.
- Liver problems: repeated nausea and vomiting, abdominal pain, abnormal tiredness, yellowing of the eyes or skin, dark urine.

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

- Blood vessel inflammation due to an allergic reaction: rash, red spots, hives and blisters in the lower part of the body.
- Acute skin reaction which 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, acute 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 ache, swollen lymph nodes, cough.
 - Shortness of breath, pain or discomfort in the chest.
 - Feeling thirsty, urinating less frequently, decrease in urine volume.

Side effects with unknown frequency:

- Anemia: tiredness, headaches, pale skin, irregular heartbeat, chest pain, cold hands, dizziness, leg muscle cramps.
- Aseptic meningitis (not caused by bacteria): confusion, fever, nausea, tiredness, sudden headaches or stiffness of the neck, sensitivity to light, vomiting.
- Inflammation of the colon (colitis due to Clostridium difficile infection): severe (watery or bloody) diarrhea, with or without fever, abdominal pain or abdominal tenderness.
- Seizures: uncontrollable shaking with or without loss of consciousness.
- Drug-induced bowel inflammation syndrome (enterocolitis): repeated vomiting (1-4 hours after taking the medicine), abdominal pain, abnormal drowsiness, diarrhea and low blood pressure. These effects may indicate a severe allergic reaction.
- Hemolytic anemia: pale skin, weakness, tiredness, shortness of breath, yellowing of the skin and/or the eyes, fever.
- Kounis syndrome (heart problems caused by an allergic reaction): chest pain, a sensation of pressure or discomfort in the chest, palpitations, nausea or vomiting, sweating, shortness of breath, tiredness, cold and clammy skin, feeling of anxiety or tendency to faint, confusion, abdominal discomfort.
- Leukopenia, neutropenia, agranulocytosis (low levels of white blood cells): fever, chills, sore throat, rapid heartbeat and breathing rate, other signs indicating an infection.
- Thrombocytopenia (a decrease in platelet levels): subcutaneous hematoma or bleeding that lasts longer than usual, tiredness and weakness.

Consult a doctor if the following side effects occur:

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

Inflammation of the tongue (a black and hairy looking tongue), tooth discoloration in children (brown, yellow or gray stains), dizziness.

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

Difficulty falling asleep (insomnia), confusion or behavioral changes.

Side effects with unknown frequency:

- Eosinophilia (an increase in the number of white blood cells): abdominal pain, rash, weight loss, wheezing.
- Linear IgA disease: a rash with blisters arranged in the shape of a ring with a central scab or with an appearance that resembles a string of pearls.
- A fungal infection that affects the mouth, stomach, urinary tract or vagina: thick white patches in the mouth, on the tongue or in the throat, sore throat. Vaginal itching, burning, rash, pain, discomfort or discharge.

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 the 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.
- 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.
- **Store in a dry place, below 25°C.**
- **Moxypen Forte 500 mg Capsules in a bottle package:** the bottle contains a desiccant. The desiccant should be left inside the bottle, and the bottle should be closed tightly after each use! The preparation can be used up to a month after first opening the bottle, but no later than the preparation's expiry date.
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to destroy 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:

Magnesium stearate.

Capsule shell: gelatin, FD&C red #3 (erythrosine E127), titanium dioxide, FD&C Blue # 2 (E132).

Printing ink: titanium dioxide, dehydrated alcohol, isopropyl alcohol, shellac, povidone, butyl alcohol, propylene glycol, sodium hydroxide.

What does the medicine look like and what are the contents of the package? A maroon opaque capsule, printed in white with MOXPEN at the top and 500 at the bottom of the cap of the capsule, and with FORTE at the top and TEVA at the bottom of the body of the capsule.

The package contains 10 or 20 capsules in a blister or 20 capsules in a bottle. Not all package sizes and types 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.

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Registration number of the medicine in the national drug registry of the Ministry of Health: 130.22.30823

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