

PATIENT INFORMATION LEAFLET

Mefenamic Acid and Dicyclomine Hydrochloride Tablets

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1. WHAT ARE XALME SPAS TABLETS AND WHAT ARE THEY USED FOR

XALME SPAS Tablets is a combination that contains medicines called mefenamic acid and dicyclomine hydrochloride. It is used for the treatment of pain relief associated with inflammation, and pain due to spasm of smooth muscles such as muscles in gastrointestinal tract and in the relief of pain and inflammation associated with menstruation. These medicines reduce pain and inflammation, and provide relief from pain and spasm.

Mefenamic Acid is most commonly used for relief of mild to moderate pain including muscle pains and pain after injury, headaches and toothaches, period pains. Dicyclomine hydrochloride Tablets work by relaxing the muscles in your stomach and gut (intestine). It stops sudden muscle contractions (spasms). In doing this, it relieves cramps, pain, bloating, wind and discomfort.

2. BEFORE YOU TAKE XALME SPAS TABLETS

DO NOT take XALME SPAS TABLETS if:

- You know that you are allergic to Mefenamic Acid or Dicyclomine or any of the other ingredients in these tablets.
- You currently have a stomach ulcer or bleeding
- You have suffered from stomach ulcers or bleeding two or more times in the past
- You suffer from inflammatory bowel disease
- You show any signs of allergy (such as asthma, hay fever or skin rash) to aspirin, ibuprofen or other NSAIDs. An allergic reaction may include swelling of the face, lips, mouth, have severe problems with your kidneys or liver
- You suffer from severe heart failure
- You had a major heart surgery
- You are in the last three months of pregnancy
- You are breast feeding.

Take special care with Mefenamic Acid Capsules and check with your doctor or pharmacist before taking your medicine if:

- You have had an ulcer or some other problem affecting your stomach, or intestines
- You have asthma or wheezing attacks (or if you have had asthma in the past)
- You have any heart, liver or kidney problems
- You are elderly
- You suffer from epilepsy (fits)
- You suffer from any abnormality of the blood

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- You are dehydrated (for example you have been losing fluid through vomiting, diarrhoea or passing too much or too little, urine (fluids))
- You have frequent headaches
- You drink alcohol
- You have a connective tissue disorder e.g. Systemic Lupus Erythematosus (SLE) resulting in joint pain, skin change and disorders of other organs
- You have a problem with the metabolism of sugar in your body
- You are trying to get pregnant
- You have glaucoma (signs include painful eyes with blurred vision)
- You have an enlarged prostate
- You have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)

Do not exceed the recommended dose or duration of treatment. If you have heart problems or suffered from a previous stroke or think that you may be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or recently have taken any other medicines, including medicines obtained without a prescription.

Xalme Spas tablets may affect or be affected by the following medicines

- Anticoagulants (drugs used to thin the blood to prevent blood clots, e.g. warfarin, heparin)
- Antiplatelet tablets (to prevent blood clots, e.g. clopidogrel)
- Antihypertensives (for the treatment of high blood pressure)
- Diuretics (to make you pass more water)
- Lithium (for depression)
- Medicines for the treatment of heart conditions (e.g. digoxin)
- Quinolone antibiotics (for an infection e.g. ciprofloxacin, norfloxacin and nalidixic acid)
- Any other NSAID (for painful or inflammatory conditions e.g. aspirin, COX-2 selective inhibitors like valdecoxib, paracoxib and refocoxib, ibuprofen)
- Mifepristone (used to terminate pregnancies)
- Methotrexate (which can be used to treat certain tumours and other diseases including psoriasis and rheumatoid arthritis)
- Ciclosporin or tacrolimus (used to suppress the body's immune system, e.g. following transplants or in diseases such as psoriasis and rheumatoid arthritis)
- Corticosteroids (used for the treatment of asthma and various inflammatory conditions e.g. beclomethasone)
- Probenecid used in treatment of swollen joints
- Drugs used in diabetes (e.g. glibenclamide)
- Drug used as antibiotics (e.g. Gentamycin, Neomycin, Kanamycin)
- Zidovudine (an anti-viral drug)
- SSRIs such as fluoxetine or sertaline (for depression).

Pregnancy and breast feeding

Ask your doctor or pharmacist for advice before taking any medicine. Mefenamic Acid may make it difficult to become pregnant.

You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. xalme Spas Tablets should, if possible not be taken during pregnancy.

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You should not take Xalme Spas Tablets if you are in the last three months of pregnancy or if you are breast feeding, speak to your doctor or pharmacist before taking these capsules. Mefenamic acid should not be given to the mother and the neonate, at the end of pregnancy, as there is a possibility of possible prolongation of bleeding time. During delivery, it may inhibit contractions of uterus resulting in delayed or prolonged delivery.

3. HOW TO TAKE XALME SPAS TABLETS

Make sure you take your tablets exactly as directed by your doctor.

The instructions will be written on the label. You should check with your doctor or pharmacist if you are not sure.

Xalme Spas tablets should be taken with or after food.

The tablets should be swallowed whole with water. Do not chew them. Do not break them unless recommended by your doctor or pharmacist.

Adults: The usual dose is One tablets two to three times each day.

For excessively heavy periods, start taking your medicine on the first day of excessive bleeding and continue as directed by your doctor.

For period pains, start taking your medicine when you first notice the pain and continue as directed by your doctor.

As a general principle, the smallest effective dose should be used.

Elderly: The adult dose can be used, although these Capsules should be used with caution in patients suffering from dehydration or kidney failure.

Children: Xalme Spas tablets are not recommended for use in children.

If you have a history of ulcers or some other problem affecting your stomach or intestines, you should inform your doctor or pharmacist if you notice any unusual symptoms affecting your abdomen(stomach) especially blood in your stomach, urine or stool, particularly if these symptoms occur during the initial phase of your treatment.

If you take more Xalme Spas tablets than you should:

If you (or someone else) take too many of these capsules, you may experience headache, nausea, vomiting, pain in abdomen, blood in stool or vomiting, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in ear, fainting, occasionally convulsions. In cases of significant poisoning acute kidney failure and liver damage are possible. Contact your doctor, or hospital immediately for advice.

If you forget to take your Xalme Spas tablets:

If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before. Do not take double the dose.

If you have any further questions about these tablets, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Xalme Spas can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

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Do not take if you have a peptic ulcer (ulcer in your stomach, or intestines) or bleeding in your stomach, or have had two or more episodes of peptic ulcer, stomach bleeding or perforation.

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heart burn
- Abdominal Pain (pains in your stomach) or other abdominal (stomach) symptoms.

If you suffer from any of the following at anytime during your treatment

STOP TAKING the medicine and see a doctor immediately.

- Pass blood in your stools/motions
- Pass loose stool (Diarrhoea)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

Other Side Effects:

- Mouth ulcers, malaise, fatigue, unexplained bruising, fever or sore throat may occasionally occur, if you notice any of these symptoms speak to your doctor as they may be signs of a blood disorder
- If a skin rash or jaundice (yellowing of the skin or whites of eyes) occur, tell your doctor
- Nausea (feeling sick), vomiting (being sick), loss of appetite
- Fits
- Rapid heart beats
- Reactions to the sun
- Blurred sight
- You may notice urinary symptoms such as blood in the urine or an increase or decrease in the amount of urine, ankle swelling, reduced salt levels in the body
- Symptoms such as sleep disturbance, depression, confusion, nervousness, hallucinations (imagining sensations), noise in the ears or impaired hearing, vertigo, dizziness, tingling or other odd sensations, problems with your eyesight or drowsiness have occasionally been reported
- Symptoms of aseptic meningitis such as, over-reaction of the skin to sunlight, persistent headache, a stiff neck, fever, drowsiness or muscle pain may occur in some patients (especially in patients with existing auto immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease)
- Medicines such as mefenamic acid may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Xalme SPAS TABLETS Store in dry place, below 30°C. Protect from Light Keep out of the reach and sight of children.

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Remember:

This medicine is for you. Only a doctor can prescribe it for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

6. FURTHER INFORMATION**What XALME SPAS TABLETS contain**

Each Xalme Spas tablet contains 250mg of the active substance, mefenamic acid and 10 mg of the active substance, dicyclomine hydrochloride

Excipients: Microcrystalline Cellulose, Maize Starch, Povidone, Propylene Glycol, Aerosil, Purified Talc, Sodium Starch Glycollate.

What Xalme Spas tablets look like and contents of the pack

Light yellow circular biconvex tablet having one side BG embossed and breakline on other side of each tablet packed in blister of Aluminium/ PVC foil.

Marketing Authorization Holder and Manufacturer:

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki-Vihar Road, Andheri (East), Mumbai – 400072.