

Package leaflet: Information for the user

Megace 160 mg Tablets

megestrol acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Megace tablets are and what they are used for
2. What you need to know before you take Megace tablets
3. How to take Megace tablets
4. Possible side effects
5. How to store Megace tablets
6. Contents of the pack and other information

1. What Megace tablets are and what they are used for

The name of your medicine is Megace tablets. Megace tablets contain the active ingredient megestrol acetate. Megestrol acetate belongs to a group of medicines called progestogens and is used to treat certain types of cancer known as hormone-dependent cancer, which include cancer of the breast.

2. What you need to know before you take Megace tablets

Do not take Megace tablets if you:

- are allergic to megestrol acetate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor if you:

- have severe liver problems
- currently suffer from, or have a history of suffering from blood clots (thrombophlebitis)
- have diabetes, as Megace tablets can increase your blood sugar levels

If you are over 65 years of age your doctor may want to monitor your kidney function from time to time, as this can sometimes decrease with age.

Other medicines and Megace tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not take Megace tablets if you are pregnant, think you may be pregnant, or if you are breast-feeding.

Driving and using machines

Megace tablets do not usually affect your ability to drive.

Megace tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Megace tablets

Always take Megace tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual dosage is 160 mg megestrol acetate per day. Tablets should be swallowed with a glass of water.

This medicine is not recommended for children.

Megace tablets should be taken for at least two months to see if they are effective. Some patients take them for many years.

Do not stop taking them, unless advised to do so by your doctor.

If you take more Megace tablets than you should

If you take more Megace than you should, go to your nearest hospital emergency department or contact your doctor immediately.

Take the empty container and any remaining medicine with you.

If you forget to take Megace tablets

If you miss a dose, do not worry. If you remember within a few hours of the missed dose take it as soon as possible, but if it is almost time for your next dose then skip the forgotten one and continue as before. Do not take a double dose to make up for the one you missed.

4. Possible side effects

As with all medicines, Megace can cause side effects although not everybody gets them.

If you notice any of the following, stop taking Megace and contact your doctor **immediately**:

- swelling of the face, lips, or tongue
- skin rash
- difficulty breathing

As these may be signs of an allergic reaction

Other side effects which may occur with Megace tablets are:

Very Common (affects more than 1 in 10 people)

- increase in appetite and weight gain (not associated with water retention)
- shortness of breath
- hot flushes, reddening of the face and neck
- high blood pressure
- increased blood sugar levels
- rounded face, sometimes called 'moon' face
- constipation
- swelling of a vein due to a blood clot
- blood clot in the lungs

Signs of a blood clot can include loss of co-ordination, slurred speech, pains in your groin, pains or numbness in your arm or leg (especially in calf of leg), shortness of breath, weakness, headache, and fainting. If you

experience any of these signs tell your doctor **immediately**.

Common (affects between 1 in 10 to 1 in 100 people)

- temporary increase in the signs and symptoms of your disease.
- changes in mood
- numbness, pain or tingling in fingers or thumb
- heart attack
- hair loss
- diarrhoea
- tiredness
- feeling weak
- impotence
- passing wind
- needing to urinate more often
- feeling sick and being sick
- changes in vaginal bleeding (breakthrough bleeding, spotting)
- build up of fluid which causes swelling (mainly in the ankles)
- pain
- rash, including hives or nettle rash (urticaria)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Megace tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after 'EXP.' The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture. They should not get too hot or damp; so do not leave your tablets near a radiator, on a window sill or in the bathroom.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Megace tablets contain

The active substance is megestrol acetate. Each tablet contains 160 mg megestrol acetate. The other ingredients are: microcrystalline cellulose, lactose monohydrate, magnesium stearate, povidone, colloidal anhydrous silica, sodium starch glycolate and purified water.

What Megace tablets look like and contents of the pack

Megace 160 mg Tablets are oval shaped biconvex tablets scored on one side and engraved with "160" on the other side and are available in blister packs of 30 tablets.

Parallel Product Authorisation Holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

Haupt Pharma Amareg GmbH, Germany.

Repackaged by

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