

Package leaflet: Information for the user

Megace 40 mg/ml Oral Suspension 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet:

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

1. What Megace Oral Suspension is and what it is used for

The name of your medicine is Megace Oral Suspension. The active ingredient in Megace Oral Suspension is called megestrol acetate.

Megace Oral Suspension belongs to a group of medicines called “progestogens” and is related to the naturally occurring hormone called progesterone.

Megace Oral Suspension helps to overcome loss of weight which often occurs in patients who are suffering from cancer or AIDS.

2. What you need to know before you take Megace Oral Suspension

Do not take Megace Oral Suspension:

- if you are allergic (hypersensitive) to megestrol acetate or any of the other ingredients of Megace Oral Suspension (listed in section 6)
- if you have a medical history of blood clots.

Warnings and precautions

Talk to your doctor or pharmacist before taking Megace Oral Suspension if you:

- currently suffer from, or have a history of suffering from swelling of a vein with blood clot formation (thrombophlebitis)

Megace Oral Suspension may raise your blood sugar if you have diabetes. If you notice that your blood sugar is higher than normal consult your doctor.

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.

Children

This medicine is not recommended for children.

Other medicines and Megace Oral Suspension

At present, no data are known regarding these effects.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take this medicines

Driving and using machines

Megace Oral Suspension does not usually affect your ability to drive.

Megace Oral Suspension contains

Megace Oral Suspension contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

This medicine contains 40 mg sodium benzoate (E211) in each 20 ml dose which is equivalent to 2 mg/ml.

This medicine contains less than 1 mmol sodium (23 mg) per 20 ml, that is to say essentially 'sodium-free'.

This medicine contains 9.8 mg of alcohol (ethanol) in each 20ml dose, which is equivalent to 0.49 mg/ml. The amount of alcohol in a 20ml dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Megace Oral Suspension

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Megace Oral Suspension is between 400 mg to 800 mg (10-20 ml) per day and is taken as a single dose. If you are 65 or older, your doctor may start you on the lowest dose, and may monitor your kidney function. Your doctor will decide on the correct dose for your condition. Always follow your doctor's instructions.

It usually takes two months of continuous treatment to see if Megace Oral Suspension is effective. Continue with Megace Oral Suspension until your doctor tells you otherwise.

If you take more Megace Oral Suspension than you should

Go to your nearest hospital Casualty Department or tell your doctor immediately. Take the empty container and any remaining medicine with you.

If you forget to take Megace Oral Suspension

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 a forgotten dose.

4. Possible side effects

Like all medicines, Megace Oral Suspension 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 Oral Suspension 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, including increased facial and body hair
- 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 the following 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)

If any of these side effects continue or become troublesome go back to your doctor.
If you notice any other side effects tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Oral Suspension

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 carton and label. Do not keep Megace Oral Suspension above 25°C.

Return any unused medicine to your pharmacist. Only keep it if the doctor tells you to.

6. Contents of the pack and other information

What Megace Oral Suspension contains

- The active substance is megestrol acetate. Each ml of oral suspension contains 40 mg/ml of megestrol acetate.
- The other ingredients are citric acid, lemon-lime flavour, polyethylene glycol (1450), polysorbate 80 (E433), sodium benzoate (E211), sodium citrate (E331), sucrose, xanthum gum (E415) and water.

What Megace Oral Suspension looks like and contents of the pack

Megace Oral Suspension is a white to cream coloured, milky oral suspension.

This medicine is supplied in a plastic bottle containing 240 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bausch Health Ireland Ltd.,
3013 Lake Drive,
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Ireland

Manufacturers:

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