

PACKAGE LEAFLET: INFORMATION FOR THE USER

MEGACE 40 mg/ml Oral Suspension

Megestrol acetate

Please read this leaflet carefully before you start taking your medicine.

This leaflet provides a summary of the information available on your medicine. 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 you want to know more or are not sure ask your Doctor or Pharmacist.

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. Further 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
- have a medical history of blood clots

Tell your doctor 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

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

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

Driving and using machines

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

Important information about some of the ingredients of Megace Oral Suspension

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 medicine.

3. HOW TO TAKE MEGACE ORAL SUSPENSION

The usual 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 double doses 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 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 sideeffects 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, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@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

You should not use this medicine after the expiry date which appears on the carton and label. Do not keep Megace Oral Suspension above 25°C. Keep all your medicines where children cannot reach or see them, preferably in a locked cupboard or medicine cabinet.

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

6. FURTHER INFORMATION

What Megace Oral Suspension contains

Megace Oral Suspension contains 40 mg/ml of megestrol acetate.

In addition to the active ingredients, Megace Oral Suspension also contains citric acid, lemon-lime flavour, polyethylene glycol (1450), polysorbate 80, sodium benzoate, sodium citrate, sucrose, xanthum gum and water.

What Megace Oral Suspension looks like

This medicine is supplied in plastic bottles containing 120 ml, 240 ml or 480 ml pack sizes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder:

PharmaSwiss Česká republika s.r.o.,
Jankovcova 1569/2c
170 00, Prague 7
Czech Republic

Manufacturer:

AndersonBrecon (UK) Ltd
Pharos House, Wye Valley Business Park,
Hay-on-Wye, Hereford,
HR3 5PG, UK

or

PharmaSwiss d.o.o.
Brodišče 32
1236 Trzin
Slovenia

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