PATIENT MEDICATION INFORMATION

MEGACE OS
Megestrol acetate Oral Suspension

Read this carefully before you start taking MEGACE OS and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MEGACE OS.

What is MEGACE OS used for?
MEGACE OS is used to treat patients with AIDS who have conditions characterized by weight loss.

How does MEGACE OS work?
It is not known how MEGACE OS increases appetite. The weight gain is associated with an increase in fat and body cell mass.

What are the ingredients in MEGACE OS?
Medicinal ingredient: Megestrol acetate
Non-medicinal ingredients: anhydrous citric acid, natural and artificial lemon-lime flavor, polyethylene glycol, polysorbate 80, purified water, sodium benzoate, sodium citrate dihydrate, sucrose and xanthan gum.

MEGACE OS comes in the following dosage forms:
Oral suspension of 40 mg/ml

Do not use MEGACE OS if:
You are allergic to megestrol acetate or any of the ingredients in MEGACE OS.
MEGACE OS should not be used as a diagnostic test for pregnancy.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MEGACE OS. Talk about any health conditions or problems you may have, including if you:

- Have diabetes. MEGACE OS may raise your blood sugar.
- Have a history of blood clots.
- Have or have had weak or brittle bones (osteoporosis/osteopenia).
- Are you pregnant, planning to become pregnant or breast feeding.
Other warnings you should know about:

The use of MEGACE OS is not intended to prevent weight loss.

Use contraception while taking this medication if you are a woman capable of becoming pregnant. MEGACE OS may cause harm to an unborn baby. Tell your physician if you become pregnant while taking this medication.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Possible drug interactions of MEGACE OS with other medications are not known.

How to take MEGACE OS:

Take MEGACE OS:

- exactly as your doctor has told you
- for at least two months, to see if it is working
- until your doctor tells you to stop
- by mouth
- as a single dose
- with the attached measuring cup

Shake container well before use.

A cup is attached to the package. It is marked at 10 mL and 20 mL. Always use this cup to measure your dose.

- 10 mL contains 400 mg.
- 20 mL contains 800 mg.

Usual adult dose: 400 mg to 800 mg (10-20 mL) per day

If you are 65 or older, your doctor may start you on the lowest dose, and may watch your kidney function. Your doctor will decide on the correct dose for your condition. Always follow your doctor’s instructions.

Overdose:

If you think you have taken too much MEGACE OS, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately even if there are no symptoms. Take the empty container and any remaining medicine with you.

Missed Dose:

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.
What are possible side effects from using MEGACE OS?

These are not all the possible side effects you may feel when taking MEGACE OS. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Weight gain
- Nausea, vomiting
- Constipation, diarrhea, flatulence
- Frequent urination
- Abnormal weakness or lack of energy
- Hot flashes, hair loss, mood change
- Rash
- Pain
- **Men** may get enlarged breasts, impotence

<table>
<thead>
<tr>
<th>Serious side effects and what to do about them</th>
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</thead>
<tbody>
<tr>
<td><strong>Symptom / effect</strong></td>
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<tr>
<td></td>
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<tr>
<td><strong>COMMON</strong></td>
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<tr>
<td>Edema (caused by excess fluid): swelling of arms or legs</td>
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<tr>
<td><strong>VERY RARE</strong></td>
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<tr>
<td>Adrenal insufficiency (adrenal glands do not make enough hormone): craving salty food, abdominal pain, nausea, vomiting, dizziness, weakness, fatigue, low blood pressure and kidney failure.</td>
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<tr>
<td>Pulmonary embolism (blockage of a major artery in the lung): sudden chest pain, shortness of breath, cough, fatigue, and heart palpitations</td>
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<td>Tumor Flare: temporary worsening of tumor symptoms,</td>
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## Serious side effects and what to do about them

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<tr>
<th>Symptom / effect</th>
<th>Talk to your healthcare professional</th>
<th>Stop taking drug and get immediate medical help</th>
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<tr>
<td>such as pain, redness, or tumor size</td>
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<tr>
<td>Vaginal bleeding: breakthrough bleeding, spotting</td>
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<td>UNKNOWN Carpal tunnel syndrome: numbness and tingling in the hand and arm</td>
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<td>Cushing’s syndrome: round and red face, high blood pressure, abdomen obesity with thin arms and legs, red stretch marks, a fat lump between the shoulders, weak muscles, weak bones, acne, and fragile skin that heals poorly. Women may have more hair and irregular menstruation.</td>
<td>✓</td>
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<td>Dyspnea: difficulty breathing, shortness of breath.</td>
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<td>Heart failure: shortness of breath, fatigue, swollen legs, rapid heartbeat</td>
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<td>✓</td>
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<tr>
<td>High blood pressure: Headaches, vision disorders, nausea, and vomiting</td>
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<td>✓</td>
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<tr>
<td>Loss of hearing</td>
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<td>✓</td>
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<td>Osteoporosis/osteopenia (weak and brittle bones): You break a bone in a situation where healthy people would not normally break a bone</td>
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<td>✓</td>
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<tr>
<td>New or worsening diabetes or hyperglycemia (high blood</td>
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<td>✓</td>
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<tr>
<td></td>
<td>Only if severe</td>
<td>In all cases</td>
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<td>Sugar): unusual thirst, hunger, frequent urination,</td>
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<td>fatigue, or weight gain or loss</td>
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<tr>
<td>Thrombophlebitis (inflammation of veins):</td>
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<td>✔</td>
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<tr>
<td>Swelling, pain and redness in an arm or leg that can</td>
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<td>be warm to the touch</td>
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9
    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store MEGACE OS at room temperature (15-30°C). Keep out of reach and sight of children.

If you want more information about MEGACE OS:
- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the
manufacturer’s website http://www.bmscanada.ca, or by calling 1-866-463-6267.

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