Package leaflet: Information for the patient

Muntel 5 mg film-coated tablets
For adults and children aged 6 years and above
Levocetirizine dihydrochloride

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

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1. What Muntel is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of Muntel.
Muntel is an antiallergic medication.

For the treatment of signs of illness (symptoms) associated with:
- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

2. What you need to know before you take Muntel

Do not take Muntel
if you are allergic to levocetirizine dihydrochloride, to cetirizine, to hydroxyzine or any of the other ingredients of this medicine (listed in section 6)
if you have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions
Talk to your doctor or pharmacist before taking Muntel.

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

Children
The use of Muntel is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

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

Muntel with food, drink and alcohol
Caution is advised if Muntel is taken at the same time as alcohol or other agents acting on the brain. In sensitive patients, the concurrent administration of cetirizine or levocetirizine and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Muntel can be taken with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Some patients being treated with Muntel may experience somnolence / drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery untill you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

Muntel contains lactose
These tablets contain lactose, if you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking them.

3. How to take Muntel

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 for adults and children aged 6 years and over is one tablet daily.

Special dosage instructions for specific populations:
Renal and hepatic impairment
Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Patients who have severe impairment of kidney function must not take Muntel.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Elderly patients aged 65 years and above
No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

Use in children
Muntel is not recommended for children under 6 years of age.

How and when should you take Muntel?
For oral use only.
Muntel tablets should be swallowed whole with water and may be taken with or without food.

How long should you take Muntel
The duration of use depends on the type, duration and course of your complaints and is determined by your physician.

If you take more Muntel than you should
If you take more Muntel than you should, somnolence can occur in adults. Children may initially show excitation and restlessness followed by somnolence.

If you think you have taken an overdose of Muntel, please tell your doctor who will then decide what action should be taken.

If you forget to take Muntel
If you forget to take Muntel, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to make up for a forgotten dose. Take your next dose at your normal time.

If you stop taking Muntel
Stopping treatment should have no negative effects. Symptoms such as pruritus may return, but they should not be any worse than they were prior to the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people
Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: may affect up to 1 in 100 people
Exhaustion and abdominal pain

Not known: frequency cannot be estimated from the available data
Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported.

At the first signs of a hypersensitivity reaction, stop taking Muntel and tell your doctor. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing) hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

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 the national reporting system:

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 Muntel

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 label and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Muntel contains
- The active substance is levocetirizine dihydrochloride.
  Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose (E464), titanium dioxide (E171), and macrogol 400.

What Muntel looks like and contents of the pack
The film-coated tablets are white to off-white, oval, with a Y logo on one side.
They are supplied in blister packs of 1, 2, 4, 5, 7, 10, 2 x 10, 10 x 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 70, 90 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

UCB (Pharma) Ireland Limited
United Drug House
Magna Drive, Magna Business Park
Citywest Road
Dublin 24, Ireland

Manufacturer
Aesica Pharmaceuticals S.r.l.,Via Praglia 15, I-10044 Pianezza (TO), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Sopras
Ireland: Muntel
Portugal: Levrix

This leaflet was last revised in 08/2018.