



ACEMAP[®], penfluridol 20 mg, tablet

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, or if you have any doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

ACEMAP tablets are like Semap tablets, the tablets contain the same quantity of active substance and the dissolution is identical.

In this leaflet:

1. WHAT ACEMAP IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACEMAP
3. HOW TO TAKE ACEMAP
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE ACEMAP
6. FURTHER INFORMATION

1. WHAT ACEMAP IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

Antipsychotic neuroleptic derivative of diphenylbutylpiperidine (nervous system).

Therapeutic indications

This medicine is indicated for the treatment of certain behavioural disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACEMAP

Contraindications

Do not take ACEMAP in the following situations:

- allergy to penfluridol or any of the other ingredients in the tablet,
- impairment of consciousness due to alcohol or other substances, coma,
- in association with dopaminergic agents, except in a parkinsonian situation, and torsadogenic drugs (excluding antiparasitic agents, neuroleptic agents, methadone), (see under "Taking or using other medicines").

Take special care with ACEMAP:

Special warnings

If you experience unexplained fever, pallor or profuse sweating you must immediately inform a doctor or emergency department.

In order to detect any cardiac problem, your doctor may decide to record an electrocardiogram.

Precautions for use

Taking alcohol is positively discouraged throughout treatment with this medicine.

In order for your doctor to be able to adapt the dosage and/or the monitoring of your treatment he will need to be told of the following situations:

- convulsions,
- liver disease,
- heart disease,
- kidney disease.

In order to detect any cardiac problem, your doctor may decide to record an electrocardiogram, since certain antipsychotic drugs can, in very rare cases, cause cardiac arrhythmias (see section 4. "Possible side effects").

This medicine should be used with caution in patients at risk of a cerebrovascular accident.

This medicine should be used with caution in elderly patients suffering from dementia.

This medicine should be used with caution if you or a member of your family has a history of blood clotting disorders, since the administration of antipsychotic drugs has been associated with the formation of blood clots.

If you are in doubt, do not hesitate to ask your doctor or pharmacist for advice.

Taking or using other medicines

This medicine should not be used with certain drugs (see "Do not take ACEMAP in the following situations").

In order to avoid any interactions between several drugs, particularly drugs used in the treatment of Parkinson's disease, methadone, neuroleptic agents that cause torsades de pointes, antiparasitic agents that cause torsades de pointes, you should routinely tell your doctor or pharmacist about any other treatment that you are currently taking.

Pregnancy

Ideally, this medicine should not be used during pregnancy. If you discover that you are pregnant, talk to your doctor as only he will be able to assess the need for continuing the treatment.

Breast-feeding

Breast-feeding is discouraged during treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

The attention of vehicle drivers and users of machinery, in particular, is drawn to the risks of reduced awareness, sleepiness, dizziness and visual problems associated with the use of this medicine.

3. HOW TO TAKE ACEMAP?

Dosage

For adults only.

The dosage is variable and should be adapted to each case. Take the dosage prescribed by your doctor.

Method and route of administration

Oral route.

Swallow the tablet whole with a little water.

Frequency and time of administration of the medicine

A single dose per week.

Duration of treatment

Do not interrupt your treatment without the agreement of your doctor.

Symptoms and instructions in the event of overdose

If you have taken more ACEMAP than you should:

An overdose may manifest itself in the form of reduced awareness, muscle rigidity and blood pressure abnormalities. If you have taken an excessive dose of this medicine, tell a doctor or emergency department immediately because of the risk of serious heart problems.

Instructions if one or more doses are missed

If you forget to take ACEMAP: Take the next dose on the usual day and at the usual time; do not take a double dose.

4. POSSIBLE SIDE EFFECTS

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

- disorders combining tremors, rigidity and/or abnormal movements,
- sleepiness,
- headaches, dizziness,
- sensation of dizziness when standing up suddenly from a lying or sitting position,
- accelerated heart rate, cardiac arrhythmia,
- nausea, vomiting,
- change in weight,
- impotence, frigidity,
- missed periods, breast enlargement, milk leaking from the nipple outside the normal breast-feeding periods.
- venous blood clots, particularly in the legs (the symptoms include swelling, pain and redness in the legs), can migrate through the blood vessels to the lungs and cause chest pain and breathing difficulties. If you notice any of these symptoms, consult a doctor immediately (see "Take special care with ACEMAP").

In exceptional cases:

- liver disorders,
- visual problems,
- weakness,
- increased salivation and sweating,
- fever, profuse sweating, pallor: a doctor or emergency department should be consulted immediately if any of these signs appears.
- elderly individuals with dementia and treated with ACEMAP to control their behaviour may be exposed to an increased risk of death compared to untreated patients.

Do not hesitate to ask the advice of your doctor or pharmacist and to report any undesirable and troublesome effect, particularly those not listed in this leaflet.

5. HOW TO STORE ACEMAP?

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of the month.

Store at 15 – 30 °C.

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

6. FURTHER INFORMATION

What ACEMAP contains

The active substance is Penfluridol; 20 mg in a 180 mg tablet. The other ingredients are lactose, maize starch, sucrose, crospovidone, magnesium stearate, indigo carmine (E132), quinoline yellow (E104).

What ACEMAP looks like and contents of the pack

This medicine comes in the form of a tablet.

The carton contains a blisterstrip of 10 tablets and package leaflet.

Manufacturer

ACE Pharmaceuticals BV
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Manufacturing authorisation 109098F

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