

PACKAGE LEAFLET: INFORMATION FOR THE USER

ACOMPLIA 20 MG FILM-COATED TABLETS (RIMONABANT)

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, ask your doctor or pharmacist.
- 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 any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ACOMPLIA is and what it is used for
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1. WHAT ACOMPLIA IS AND WHAT IT IS USED FOR

The active ingredient of ACOMPLIA is rimonabant. It works by blocking specific receptors in the brain and fat tissues called CB1 receptors. ACOMPLIA is indicated in the treatment of obesity and management of body weight as adjunct to diet and exercise.

2. BEFORE YOU TAKE ACOMPLIA

Do not take ACOMPLIA

- if you are allergic (hypersensitive) to rimonabant, or any of the other ingredients of ACOMPLIA,
- if you are breast-feeding.

Take special care with ACOMPLIA

Tell your doctor before you start to take this medicine:

- if you have impaired liver function
- if you have severely impaired renal function
- if you are currently being treated for epilepsy
- if you are less than 18 years of age. There is no information available on the use of ACOMPLIA in people under 18 years of age.

Taking other medicines

The activity of ACOMPLIA is increased by simultaneous use of some drugs (so-called CYP3A4 inhibitors) such as:

- itraconazole (antifungal medicine)
- ketaconazole (antifungal medicine)
- ritonavir (medicine for the treatment of HIV infections)
- telithromycin (antibiotic)
- clarithromycin (antibiotic)
- nefazodone (anti-depressor)

Please inform your doctor or pharmacist if you are taking or have recently taken the above mentioned medicines or any other medicines, including those obtained without a prescription such as St John's wort, rifampicin (antibiotic), medicines for weight loss, medicines to improve blood lipids (fats), antidiabetes medicines and medicines to treat epilepsy (e.g. phenytoin, phenobarbital, carbamazepin) or depression.

Pregnancy and breast-feeding

ACOMPLIA should not be taken during pregnancy.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking ACOMPLIA.

Do not take this medicine when breast-feeding. Tell your doctor if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

At the recommended dose, ACOMPLIA is not expected to reduce your ability to drive and use machines.

Important information about some of the ingredients of ACOMPLIA

ACOMPLIA tablets include lactose. If you are intolerant to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ACOMPLIA

Always take ACOMPLIA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one 20 mg tablet to be taken once daily in the morning before breakfast. Swallow the tablet whole.

You need to start and continue a reduced calorie diet and a physical activity program to get best results. Your doctor should recommend the type of diet and the level of physical activity required, that suits your specific condition and overall health.

Taking ACOMPLIA with food and drink

ACOMPLIA should be taken once daily in the morning before breakfast.

If you take more ACOMPLIA than you should

If you take more ACOMPLIA than you should tell a doctor or pharmacist.

If you forget to take ACOMPLIA

Take it as soon as you remember but do not take a double dose to make up for any forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, ACOMPLIA can cause side effects, although not everybody gets them. Very common side effects, that affect more than 1 per 10, that have occurred in patients on ACOMPLIA include: nausea and upper respiratory tract infection.

Common side effects, that affect more than 1 per 100 but less than 1 per 10, that have occurred in patients on ACOMPLIA include: upset stomach, vomiting, trouble with sleeping, nervousness, depression, irritability, dizziness, diarrhoea, anxiety, itching, excessive sweating, muscle cramps or spasm, fatigue, bruising, tendon pain

and inflammation (tendonitis), memory loss, back pain (sciatica), altered sensitivity of the hands and feet, hot flush, fall, influenza, and joint sprain.

Uncommon side effects, that affects less than 1 per 100 but more than 1 per 1000, that have occurred in patients on ACOMPLIA include:

Sleepiness (lethargy), night sweats, panic symptoms, hiccups, anger, restlessness (dysphoria), emotional disorder.

Rare side effects, that affect less than 1 per 1000, that have occurred in patients on ACOMPLIA include: hallucinations.

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.

5. HOW TO STORE ACOMPLIA

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ACOMPLIA contains

The active substance is rimonabant. One film-coated tablet contains 20 mg rimonabant.

The other ingredients are:

Tablet core: maize starch, lactose monohydrate, povidone K 30 (E1201), croscarmellose sodium (E468), sodium laurilsulfate (E487), microcrystalline cellulose (E460), magnesium stearate

Tablet coating: lactose monohydrate, hypromellose 15 mPa.s (E464), titanium dioxide (E171), macrogol 3000

Tablet polishing: carnauba wax (E903)

What ACOMPLIA looks like and contents of the pack

ACOMPLIA 20 mg is supplied as teardrop-shaped, white film-coated tablets debossed with “20” on one side.

ACOMPLIA is available in blister packs of 14, 28, 56, 84 and 98 tablets, in perforated unit dose blister packs containing 70 x 1 tablets, and in white plastic bottles containing 28, 98 and 500 tablets.

Not all pack sizes may be marketed.

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This leaflet was last approved in June 2006.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.eu.int/>.