

User Information Pamphlet
Apiretal 325/500mg Comprímidos Bucodispersables
(Paracetamol)

Read the whole of this prospectus in detail, because it contains information that will be important to you.

This medication can be obtained without a prescription for the treatment of minor afflictions without the intervention of a doctor. However, you must use APIRETAL SUPOSITORIOS NIÑOS with care to obtain the best results.

-Keep this prospectus; you may need to read it again.

-If you have any doubts, consult your doctor or pharmacists.

This medicine has been prescribed to you and must not be given to others. It may harm them, even when their symptoms are the same as yours.

In this prospectus:

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1. WHAT ARE apiretal 325/500mg Comprímidos Bucodispersables AND WHAT ARE THEY USED FOR

Apiretal 325/500mg Comprímidos Bucodispersables belong to the analgesic and antipyretic medicine group.

This medicine is indicated in febrile states of for the relief of weak or moderate pain.

2. BEFORE TAKING apiretal 325/500mg Comprímidos Bucodispersables

Do not take apiretal 325/500mg Comprímidos Bucodispersables:

-If you are allergic (hypersensitive) to paracetamol or any of the other components of apiretal 325/500mg Comprímidos Bucodispersables.

-If you suffer from an illness of the liver.

-If you have phenylketonuria (a hereditary illness diagnosed at birth).

Be especially careful with apiretal 325/500mg Comprímidos Bucodispersables

-Do not exceed the dose indicated in section 3.

-Patients with kidney, heart or lung diseases or those with anaemia (decrease in the amount of haemoglobin in the blood, as a result or not of a decrease in red blood cells) should consult their doctor before taking this medicine.

-The consumption of alcoholic beverages can provoke paracetamol to cause liver damage.

-If the pain continues for more than 3 days in children or 5 in adults (2 days for a sore throat) or a temperature for more than 3 days, or if symptoms worsen or new ones appear, you should interrupt the treatment and consult your doctor.

Use of other medicines

Inform your doctor or pharmacist if you are using or have recently used other medicines, including those acquired without a prescription.

Particularly if you are using medicines which include any of the following principal components, as it may be necessary to adapt the dose or interrupt the use of one of them:

- Antibiotics (chloramphenicol).
- Oral anticoagulants (acenocoumarol, warfarin).
- Oral forms of contraception and treatments with estrogens.
- Antiepileptics (lamotragine, phenytoin, or other hydantoin, phenobarbital, metylphenobarbital, primidone, carbamazepine).
- Antituberculosis (isoniazid, rifampicin).
- Barbiturates (used to induce sleep, sedatives and anticonvulsives).
- Activated carbon, used for the treatment of diarrhoea and gases.
- Cholestyramine, used to lower the amount of cholesterol in the blood.
- Medicines used for the treatment of gout (probenecide, sulfinpyrazone).
- Medicines used for the relief of spasms, or contractions of the stomach, intestine and the bladder (anticholinergics).
- Metoclopramide and domperidone (used to avoid nausea and vomiting).
- Propranolol used in the treatment of high blood pressure (hypertension) and alterations in the heart's rhythm (cardiac arrhythmias).
- Zidovudine (used in the treatment of patients infected by the human immunodeficiency virus, which causes AIDS).

Interference with analytic tests:

If you are going to have an analytic test (including blood or urine tests, skin tests that use allergens etc) tell the doctor that you are taking this medicine, as it can alter the results of these tests.

Taking apiretal 325/500mg Comprimidos Bucodispersables with food or drink

Apiretal 325/500mg Comprimidos Bucodispersables can be taken with food and drink. The use of paracetamol by patients who habitually drink alcohol (3 or more measures daily) can cause liver damage.

Pregnancy and during breast feeding

Consult your doctor or pharmacist before taking any medicine.

Although controlled studies do not exist, teratogenic reactions have not been observed in women. Even so, as a general rule, its use during the first trimester of pregnancy is not recommended, and in the case of doing so it should be done valuing the possible risks and benefits of the treatment. Paracetamol passes through to maternal milk so women breast feeding must consult with their doctor before using this medicine.

Use in children

Apiretal 325/500mg Comprimidos Bucodispersables are not suitable for children weighing less than 19kg. For children of between 14 and 19kg apiretal 250mg orodispersible tablets are recommended.

Apiretal 325/500mg Comprimidos Bucodispersables are not indicated for children weighing less than 27kg. For children of between 14 and 19kg the use of apiretal 250mg

Comprimidos Bucodispersables are recommended, and for those of 19 to 27kg, the use of apiretal 325mg orodispersible tablets.

Driving and using machines

No effect on the capacity to drive or use machines has been reported.

Important information about some of the components of apiretal 325/500mg

Comprimidos Bucodispersables.

This medicine can be prejudicial to people with phenylketonuria because it contains aspartame which is a source of phenylalanine.

3. HOW TO TAKE apiretal 325/500MG Comprimidos Bucodispersables

Follow these instructions, unless your doctor has given you other indications.

Consult your doctor or pharmacist if you have doubts.

Remember to take your medication.

Apiretal 325/500mg Comprimidos Bucodispersables are administered orally.

Apiretal 325/500mg Comprimidos Bucodispersables are indicated for weights of 27kg or above.

The recommended daily dose of paracetamol depends on weight and is approximately 60mg/kg/day, which is divided into 4 or 6 doses, so 15mg/kg every 6 hours or 10mg/kg every 4 hours.

-In children of between **20 and 26kg (6 to 10 years old)** the dose is one 325mg tablet, repeated if necessary 4 hours later, **up to a maximum of 4 tablets daily**.

-In children weighing between **27 and 39 kg (8 to 13 years old)** the dose is one 500mg tablet, repeated if necessary 6 hours later, **up to a maximum of 4 tablets daily**.

-In children with a weight of **40kg and above (from 12 to 15 years old onwards)** the dose is of one 500mg tablet, repeated if necessary 4 hours later, **with a maximum of 6 tablets daily**.

Administration of the product is contingent on the apparition of symptoms of pain or fever. As these disappear medication must be suspended.

Method of administration

Allow the tablet to break up in the mouth before swallowing. It can also be broken up in water.

If you take more apiretal 325/500mg Comprimidos Bucodispersables than you should

If you have taken more paracetamol than you should immediately consult your doctor or pharmacist or phone the Toxicology Information Service on 915620420, indicating the medicine and the amount used. It is recommended to take the container and information pamphlet to health staff.

If you have overdosed you must go to a medical centre quickly even if you have no symptoms as these often do not manifest themselves until 3 days after the ingestion of the overdose even in cases of extreme intoxication. Symptoms of overdose can be: dizziness, vomiting, loss of appetite, yellowing of the skin and eyes (jaundice) and abdominal pains.

The ingestion of more than 6g in adults and more than 100mg per kg of weight in children is considered an overdose of paracetamol. Treatment of an overdose is more effective if it is started within the first 4 hours following ingestion of the medicine.

In the case that the patient is being treated with barbiturates or suffers from chronic alcoholism he or she can be more susceptible to an overdose of paracetamol.

In general a symptomatic treatment is undertaken.

If you forget to take apiretal 325/500mg orodispersible tablets

Do not take a double dose to compensate the forgotten ones.

In the case that you have forgotten one dose take another as quickly as possible and then continue with the habitual schedule. However, if the time of your next dose is very near, skip the dose you forgot and take the next dose at the usual time.

4. POSSIBLE SIDE EFFECTS

As with all medicines, apiretal 325/500mg Comprimidós Bucodispersables can produce adverse effects, even though not everyone suffers from them.

Adverse reactions to paracetamol are, on the whole, rare (at least 1 in every 10000 patients) or very rare (less than 1 every 10000 patients). In very rare cases high or prolonged doses can damage the liver. In very rare cases skin rashes can appear and alterations of the blood such as neutropenia or leukopenia.

If you consider any of the side effects you suffer to be serious or if notice any other adverse effect not mentioned in this pamphlet inform your doctor or pharmacist.

5. CONSERVATION of apiretal 325/500mg Comprimidós Bucodispersables.

Maintain apiretal 325/500mg Comprimidós Bucodispersables out of reach and sight of children.

It does not need special conditions for its conservation.

Do not use apiretal 325/500mg Comprimidós Bucodispersables after the expiry date that appears on the cardboard container after 'CAD'. The expiry date is the last day of the month indicated. Medicines must not be disposed of in the drains or thrown away. Ask your pharmacist how to dispose of any containers or unneeded medicines. This way you will help look after the environment.

6. ADDITIONAL INFORMATION

Composition of apiretal 325/500mg Comprimidós Bucodispersables

-The principal ingredient is paracetamol.

-The other components are: ethylcellulose, microcrystalline cellulose, crospovidone, aspartame (E-951), colloidal silica, mannitol, talc, magnesium stearate, and essence of grape.

Appearance of the product and contents of the container

apiretal 325/500mg orodispersible tablets are presented as orodispersible tablets in boxes of 24/12 tablets.

Holder of the authorisation for the commercialisation and fabrication of the product.

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This information prospectus was approved in February 2009.