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 100 mg/ml SOLUCIÓN ORAL 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:
1. What are apiretal 100 mg/ml solución oral and what are they used for?
2. Before using apiretal 100 mg/ml solución oral
3. How to use apiretal solución oral
4. Possible adverse effects
5. Storage of apiretal 100 mg/ml solución oral

1. What IS apiretal 100 mg/ml solución oral AND WHAT IS IT USED FOR

Apiretal 100 mg/ml solución oral 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 100 mg/ml solución oral

Do not take apiretal 100 mg/ml solución oral
- If you are allergic (hypersensitive) to paracetamol or any of the other components of apiretal 100 mg/ml solución oral.
- If you suffer from an illness of the liver.

Be especially careful with apiretal 100 mg/ml solución oral
- 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 anticoagulents (acenocoumarol, warfarin).
- Oral forms of contraception and treatments with estrogens.
- Antiepileptics (lamotrigine, phenytoin, or other hydantoins, phenobarbital, methylphenobarbital, 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, sulfisoxazole).
- 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 100mg/ml oral solution with food and drink
Apiretal 100 mg/ml solución oral can be diluted in water, milk or fruit juices. 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
You are advised to consult a doctor before administering it to children under 3.

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 100 mg/ml solución oral. This medicine can produce allergic reactions because it contains
azorubine (E-122). It can provoke asthma, particularly in patients allergic to acetylsalicylic acid.

3 How to take apiretal 100 mg/ml solución oral.

Follow these instructions unless your doctor has given you others. Consult your doctor or pharmacist if you have doubts.

Remember to take your medicine.

apiretal 100 mg/ml solución oral is administered orally. It is designed for use in children weighing between 3 and 32 kg (approximately 0 to 10 years old).

The dose of apiretal 100 mg/ml solución oral depends on the weight of the child. The approximate age of the child is given for information purposes.

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.

It is recommended to administer the dose in drops (4mg/drop) for children of 0 to 3 years old, with the top and dropper (1) provided with the 15 and 30ml containers. With children of 3 or more years old it is recommended to administer the oral solution in millilitres (ml) (100mg/ml) with the syringe for oral use (2) provided with the 60 and 90 ml containers.

For the administration of **15mg/kg every 6 hours**, the guideline is the following:

<table>
<thead>
<tr>
<th>Weight of the child</th>
<th>Age (guidance only)</th>
<th>Volume in ml</th>
<th>mg of paracetamol</th>
<th>Equivalent in drops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 4 kg</td>
<td>0-3 months</td>
<td>0,6 ml</td>
<td>60 mg</td>
<td>15 drops</td>
</tr>
<tr>
<td>Up to 8 kg</td>
<td>4-11 months</td>
<td>1,2 ml</td>
<td>120 mg</td>
<td>30 drops</td>
</tr>
<tr>
<td>Up to 10,5 kg</td>
<td>12-23 months</td>
<td>1,6 ml</td>
<td>160 mg</td>
<td>--</td>
</tr>
<tr>
<td>Up to 13 kg</td>
<td>2-3 years old</td>
<td>2,0 ml</td>
<td>200 mg</td>
<td>--</td>
</tr>
<tr>
<td>Up to 18,5 kg</td>
<td>4-5 years old</td>
<td>2,8 ml</td>
<td>280 mg</td>
<td>--</td>
</tr>
<tr>
<td>Up to 24 kg</td>
<td>6-8 years old</td>
<td>3,6 ml</td>
<td>360 mg</td>
<td>--</td>
</tr>
<tr>
<td>Up to 32 kg</td>
<td>9-10 years</td>
<td>4,8 ml</td>
<td>480 mg</td>
<td></td>
</tr>
</tbody>
</table>

For a direct calculation it is also possible to multiply the weight of the child in kg by 0.15; the result is the ml of apiretal 100 mg/ml solución oral to be administered.

These doses can be repeated every 6 hours.

If after 3-4 hours of administration the required effects are not obtained the dose can be put forward to every 4 hours, in this case 10mg/kg shall be administered,
Administration of the product is contingent on the apparition of symptoms of pain or fever. As these disappear medication must be suspended.

**Instructions for the correct administration of the product**

**15 or 30ml bottles with security top and dropper (2ml):**

1 and 2- Hold the bottle firmly with one hand. With the other, hold the top between the thumb and index finger over the two triangles indicated on the lid with the word ‘PRESS’.

3- To open, press down on the triangles and unscrew the lid turning to the left, (anticlockwise). Extract the necessary quantity with the help of the top and dropper. Administer directly or dilute the drops in water.

**60 and 90ml bottles with a security screw top, with a syringe for oral administration (5ml):**

1- Open the bottle following the instructions indicated on the lid (the first time you open it the seal will break).

2- Introduce the syringe for oral use, pressuring on the orifice of the perforated lid.

3- Invert the bottle and take out the necessary dose.

4- Administer directly or dilute with water, milk or fruit juice.

5- The syringe for oral use must be washed with water after each use.

Cover the bottle well after each administration.

**If you take more apiretal 100 mg/ml solución oral 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 100 mg/ml solución oral**

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 100 mg/ml solución oral 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 100 mg/ml solución oral

Maintain it out of the sight and reach of children.

Conserve the solution in its original container. It does not require any special means of conservation.

Do not use apiretal 100 mg/ml solución oral after the expiry date that appears on the cardboard container after ‘CAD’. The expiry date is the last day of the month indicated.

Once open use the contents within 6 months.

Medicines must not be disposed of in the drains or thrown away. Leave unwanted medicines and containers at the SIGRE point in a chemist. 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 100 mg/ml solución oral

- The principal ingredient is paracetamol. Each ml of solution contains 100mg of paracetamol.
- Other components are: polyethylene glycol, glycerol (E-422), essence of raspberry, sodium saccharin (E-954), azorubine (carmoisine) (E-122) and water.

Appearance of the product and container contents

apiretal 100 mg/ml solución oral is presented as a transparent red solution and with an aroma characteristic of raspberry, bottled in a plastic bottle of 15, 30, 60 or 90 ml.

- **30ml bottles**: Plastic bottles with a security lid and 2 ml dropper.
- **60 or 90 ml bottles:** Plastic bottles with a security lid and a syringe for oral use of 5ml.
In any case the bottles have a different capacity depending on the volume they contain.

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

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Tel: 93 314 80 11   Fax: 93 314 40 96

**Responsible for fabrication.**
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