Metalgial 500mg/ml oral drops in solution
(sodium metamizole)

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 Metalgial 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 Metalgial and what are they used for?
2. Before using Metalgial
3. How to use Metalgial
4. Possible adverse effects
5. Storage of Metalgial

1. WHAT IS METALGIAL AND WHAT IS IT USED FOR?
Metamizole, the principal ingredient of Metalgial 500mg/ml oral drops in solution, is an analgesic and antipyretic medicine for the treatment of pain and fever. It belongs to the pyrazalone group of medicines.

Metalgial 500mg/ml oral drops in solution is used in the treatment of acute post operation or post trauma pain, colic pain or pain originating from a tumour. It is also used in cases of high temperatures which do not respond to other antithermics.

2. BEFORE TAKING METALGIAL

Do not take Metalgial:
- If your doctor has not prescribed this medicine.
- If you have a history of hyper sensibility (allergy) to metamizole or any other pyrazolonic derivatives or any of the other components of this medicine.
- If you have reacted with a decrease in the number of white blood cells (agranulocytosis) after using these substances.
- If you have had symptoms of asthma, rhinitis or hives (red rashes or wheals on the skin which can itch) after the administration of aspirin, paracetomol or anti inflammarories, not steroids, as you may be predisposed to be sensible to metamizole (crossed sensibility).
- If your doctor has diagnosed you with intermittent acute porphyria (a disorder of the blood pigments metabolism which form part of the haemoglobin).
- If your doctor has diagnosed a congenital deficiency of dehydrogenated glucose-6-phosphate (a lack of a protein present in the red blood cells which can cause a type of anaemia known as hemolytic anaemia).
- If you have suffered alterations of the functioning of bone marrow, for example after receiving chemotherapy, or if you have had blood illnesses.

Be especially careful with Metalgial
- If you present dizziness, breathing difficulty, rhinitis, facial swelling (angioneurotic edema), decrease in blood pressure, the sudden apparition of red stains on the skin, you must suspend the treatment and consult your doctor immediately, as it could be the sign of a serious allergic reaction (anaphylaxis/anaphylactic shock).
- If during the treatment you have a high temperature, shivers, sore throat inflammation in the mouth, nose or throat, injuries in the oral or genital mucosa you must suspend the treatment and consult your doctor immediately as this could indicate a decrease in the number of white blood cells (agranulocytosis).
- If you have had an allergic reaction to metamizole, you must not take medicine with it again.
- If you suffer asthma syndrome due to painkillers, bronquial asthma, especially with rinossinusitis and nasal polyps, chronic hives, or if you are intolerant to colouring agents and/or preservatives or alcohol, as the risk of possible serious allergic reactions is greater.
- If you have pre existing problems of low blood pressure (below 100mmHg) or have unstable circulation or present a high temperature as the risk of a sharp drop in blood pressure is greater.
- If you have a diminished hepatic or renal function.

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

If you administer metamizole in conjunction with cyclosporine, you can reduce the levels of cyclosporine in the blood, as such these need to be measured regularly.

Taking Metalgial with food and drink:
Combined with alcohol the effects of both substances may be increased.

Pregnancy and while breast feeding:
Consult your doctor or chemist before taking any medicine.

It is recommended not to administer the medicine during the first and last trimester of pregnancy. In the second trimester it shall only be used once the doctor has weighed up the benefit/risk balance.

The metalobites of metamizole are excreted with maternal milk, as such breast feeding must be avoided for the 48 hours following its administration.
**Driving and the use of machines:**
Although adverse effects on the capacity to concentrate and react are not expected, with higher doses, among those recommended, it should be born in mind that these capacities could be affected and the use of machines, driving and other dangerous activities should be avoided. This is particularly true when alcohol has been consumed.

**Important information about some of the components of Metalgial:**
Patients with low sodium diets must bear in mind that this medicine contains 35 mg (1.5 mmol) of sodium per ml (20 drops).

**3. How to take Metalgial**

Follow the administration instructions given by your doctor exactly. Consult your doctor or chemist if you have doubts.

If you consider that the effect of Metalgial is too strong or weak, communicate this to your doctor or chemist.

This medicine must be administered orally. The habitual dose is:

- Adults and teenagers older than 15: 500 mg (20 drops), 3 or 4 times a day.
- Children between 5 and 14: 10-15 drops up to 4 times a day.
- Children breast feeding over 4 months old up to 4 year olds: 2-6 drops up to 4 times a day.

A clear therapeutic benefit can be expected 30 to 60 minutes after administration. Your doctor will indicate the duration of your treatment with Metalgial.

**Dosage in those with renal or hepatic insufficiency:**
In patients with a diminished renal or hepatic function, as with elderly patients or those with a generally diminished condition, the administration of high doses should be avoided.

**Instructions for the correct administration of the product:**
The drops are administered orally with a little water.

1. To extract the jar’s security lid, press on its surface (A) while at the same time unscrewing in an anticlockwise direction (B).

2. Once the top has been extracted place the jar in a vertical and totally inverted position. **DO NOT SHAKE. WAIT A FEW SECONDS UNTIL THE FIRST DROP COMES OUT.**
If you take more Metalgial than you should:
Nausea, vomiting, abdominal pain and deterioration of the renal function could appear, and in very rare cases, vertigo, drowsiness, coma, convulsions and decreased blood pressure.
After the administration of very high doses of metamizole a red colouration of urine may occur, this disappears on suspension of the treatment.
In the case of overdose or accidental ingestion, immediately consult your doctor or chemist, or the Toxicology Information Service, telephone: 915620420.

If you forget to take Metalgial:
Do not take a double dose to compensate those missed.
If you have any other doubt about the use of this product, ask your doctor or chemist.

4. POSSIBLE SIDE EFFECTS
As with all medicines, Metalgial can produce side effects, although not everyone suffers from them.

Infrequent side effects, which affect between 1 and 10 of every 1000 people.

- Drug induced rashes
- Decrease in blood pressure

Rare side effects, which affect between 1 and 10 of every 10000 patients.

- The weakest allergic reactions habitually manifest themselves as skin and mucosa symptoms (for example, itching, burning, reddening, hives, swelling), breathing difficulty, and with less frequency gastrointestinal disturbances. These weak reactions can progress till they are serious. In patients with asthmatic symptoms caused by painkillers, these reactions of intolerance habitually manifest themselves as asthma attacks.
  - Skin rashes
  - Decrease in the number of white blood cells (leucopenia).

Very rare side effects, which affect less than 1 every 10000 people.

- Serious allergic reactions which can appear with generalised hives, swelling of feet, hands, lips, throat and respiratory paths (angyoedema), decrease in the passing of air to the lungs due to the sharp closure of the bronchi, alterations of the cardiac rhythm, decreased blood pressure (sometimes preceded by an increase in blood pressure) and circulatory crash, which can put your life at risk. These reactions can appear even if you have already taken metamizole on other occasions without complications and usually appear in the first hour following administration.
  - Very serious cutaneous blistering reactions (Stevens-Johnson syndrome or Lyell’s syndrome).
  - Decrease in the number of platelets in the blood (thrombocytopenia).
  - Serious decrease in the number of white blood cells (agranulocytosis).
- Alteration in the functioning of the kidneys with a decrease or suppression of the quantity of urine, increase in the elimination of proteins in the urine and/or kidney inflammation (sharp interstitial nephritis).

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

5. Conservation of Metalgial

Keep out of sight and reach of children.

It does not require special conservation conditions.

Do not use Metalgial after the expiry date which appears on the 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. 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 Metalgial
The principal ingredient is sodium metamizole. Each ml (20 drops) of solution contains 500mg of sodium metamizole, which is equivalent to 467.3mg of metamizole. The other components are: dibasic dodecahydrate sodium phosphate, dehydrated sodium phosphate, purified water, aroma of raspberry and sodium saccharin.

Product appearance and container contents
Metalgial 500mg/ml is presented as an oral solution. Each container contains 20ml of solution and a medicine dropper.

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

Holder of the authorisation
LABORATORIOS ERN, S.A.
C/ Pedro IV, 499
08020 Barcelona
España

Producer
ABC Farmaceutici S.p.A.
Canton Moretti 29 – Loc. S. Bernardo
10090 Ivrea (TO) – ITALIA

This product was approved in April 2010.
Detailed and updated information about this product is available on the webpage of the Spanish Agency for Medicines and Health Products (AEMPS)
http://www.aemps.gob.es/