

Read all of this leaflet carefully before you start using this medicine because it contains important information for your treatment.

If you have any further questions or are in doubt, ask your doctor or pharmacist for more information.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.

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.

In this leaflet:

1. What TOT'HEMA, oral solution in ampoule is and what it is used for?
2. What you need to know before taking TOT'HEMA, oral solution in ampoule?
3. How to take TOT'HEMA, oral solution in ampoule?
4. Possible side effects?
5. How to store TOT'HEMA, oral solution in ampoule?
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1. WHAT TOT'HEMA, oral solution in ampoule IS AND WHAT IT IS USED FOR?

TOT'HEMA belongs to a class of medicines called antianaemics (Iron supplement).

This medicine is an iron supplement. It is prescribed as:

- a curative treatment of iron deficiency anaemia in adults, children and infants
- a preventive or curative treatment of iron deficiency in pregnant women, infants and children when the dietary intake of iron is inadequate.

2. WHAT YOU NEED TO KNOW BEFORE TAKING TOT'HEMA, oral solution in ampoule?

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Do not take TOT'HEMA:

- If you are allergic (hypersensitive) to the active substances (ferrous gluconate, manganese gluconate and copper gluconate) or any of the other ingredients of this medicine (listed in section 6).
- If you have an excess of iron, non-iron deficiency anaemia (such as thalassemia, refractory anaemia, anaemia due to medullary insufficiency and inflammatory anaemia).

Take special care with TOT'HEMA:

- The prevention of infantile deficiency is based on the early introduction of a diversified diet.
- This medicine contains 3 g of sucrose per ampoule. This should be taken into account in the daily ration in the event of a low-sugar diet or diabetes. This medicine is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrose-isomaltase insufficiency (rare hereditary diseases).
- This medicine contains 0.08g of glucose per ampoule. This should be taken into account in the daily ration in

the event of a low-sugar diet or diabetes. This medicine is not recommended in patients with glucose-galactose malabsorption syndrome.

- The presence of glucose and sucrose in this medicinal product may be harmful to teeth when taken over an extended period (e.g. for 2 weeks or more).
- The medicine contains small amounts of alcohol, less than 100 mg per ampoule.

Taking other medicines

You must wait for at least 2 hours between taking TOT'HEMA and one of the following medicines:

- antibiotics in the family of cyclines or fluoroquinolones (medicines used to treat certain infections).
- Diphosphonates (medicines used to treat bone diseases).
- Penicillamine (medicine used to treat rheumatoid arthritis and Wilson's disease).
- Thyroxin containing medicines (medicines used for thyroid treatment).
- Topical gastrointestinal medicines such as salts, oxides and hydroxides of magnesium, aluminium and calcium.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Excessive consumption of tea inhibits the absorption of iron. This is why you should avoid taking TOT'HEMA at the same time as tea.

Pregnancy and breast-feeding

Under normal conditions of use, this medicine can be taken during pregnancy.

If you are breast-feeding, talk to your doctor before taking this medicine.

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

Important information about some of the ingredients of TOT'HEMA

This medicine contains glucose, sucrose and alcohol (see section 'Take special care with TOT'HEMA').

3. HOW TO TAKE TOT'HEMA, oral solution in ampoule?

The usual dose is:

- **As a curative treatment of iron deficiency and iron deficiency anaemia:**

For adults: 100 to 200 mg of elemental iron per day, i.e. 2 to 4 ampoules per day.

For infants from 1 month and children: 5 to 10 mg of elemental iron/kg/day.

- **As a preventive treatment for iron deficiency:**

For pregnant women: 50mg of elemental iron per day, i.e. 1 ampoule per day during the last 2 trimesters of pregnancy (or from the 4th month).

Method and route of administration:

This medicine is taken orally.

Take the ampoules diluted in water, sweetened or not, or any other non-alcoholic drink.

Frequency of administration

Take preferably before meals, but the time of administration and sometimes the dose can be adapted according to digestive tolerance.

Duration of treatment

It must be adequate to correct the anaemia and replenish iron stores, which, for adults, are 600 mg for women and 1200 mg for men.

Anaemia due to iron deficiency: 3 to 6 months depending on the depletion of the stores, to be prolonged if the cause of anaemia is not controlled.

Respect the duration of treatment.

If you take more TOT'HEMA than you should, inform your doctor or pharmacist:

The following symptoms may develop following massive ingestion of iron salts, particularly in children less than two years old: signs of irritation and gastrointestinal necrosis, with, in most cases, nausea, vomiting and state of shock.

Treatment should be given as soon as possible through gastric lavage using a 1% solution of sodium bicarbonate.

Use of a chelating agent is efficient, the most specific being deferoxamine, mainly when the serum iron concentration is higher than 5 µg/ml. A state of shock, dehydration and acido-basic balance disturbance are treated in the standard practice.

If you forget to take TOT'HEMA:

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, TOT'HEMA can cause side effects, although not everybody gets them:

- Uncommon side effects (affecting 1 to 10 patients in 1 000):

- Digestive disorders: gastric burning, nausea, vomiting, constipation, diarrhoea.
- Stools normally black.
- Brown or black marks on the teeth, reversible on stopping treatment. They can also be attenuated by brushing the teeth.

- Side effects with unknown frequency:

- Potential allergic reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Competent Authority for pharmacovigilance in your country. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOT'HEMA, oral solution in ampoule?

Keep out of sight and reach of children.

Do not use TOT'HEMA after the expiry date states on the box. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 TOT'HEMA contains

The active substances are:

Iron 50.00 mg
Corresponding to ferrous gluconate 399.73 mg

Manganese 1.33 mg
Corresponding to manganese gluconate 10.78 mg

Copper 0.70 mg
Corresponding to copper gluconate 5.00 mg

For a 10 ml ampoule.

The other ingredients are:

Glycerol, liquid glucose, sucrose, anhydrous citric acid, sodium citrate, sodium benzoate, polysorbate 80, caramel colorant E150c (glucose, ammonium hydroxide), tutti frutti flavouring (isoamyl acetate, isoamyl butyrate, benzaldehyde, ethyl methylphenylglycidate, gamma undecalactone, ethylvanilline, alcohol, water) and demineralised water.

What TOT'HEMA looks like and contents of the pack

This medicine is in the form of oral ampoule.

Each box contains 20 ampoules.

Marketing authorisation holder

LABORATOIRE INNOTECH INTERNATIONAL

22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL
FRANCE

Manufacturer

INNOTHERA CHOUZY
RUE RENE CHANTEREAU
CHOUZY SUR CISSE
41150 VALLOIRE SUR CISSE
FRANCE

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