ANNEX IIIB

Package leaflet: Information for the user

TOT'HEMA, oral solution in ampoule

Iron / manganese / copper

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is 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 you take 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
6. Contents of the pack and other information

1. What TOT'HEMA, oral solution in ampoule is and what it is used for

Pharmacotherapeutic group: COMBINATION, ANTIANAEMIC, MINERAL SUPPLEMENT, OLIGOELEMENT - ATC code: B03AE10: ANTIANEMIC PREPARATIONS, IRON IN OTHER COMBINATIONS, VARIOUS COMBINATIONS.

TOT'HEMA belongs to antianaemic drugs (Iron supplement).

This medicine is an iron supplement. It is indicated for:
- Curative treatment of iron deficiency anaemia in adults, children and infants,
- Preventive or curative treatment of iron deficiency in pregnant women, in infants and in children when the dietary intake of iron is not sufficient.

2. What you need to know before you take TOT'HEMA, oral solution in ampoule

If you have been told by your doctor that you are intolerant to some sugars, contact him/her before taking this medicine.

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, an anaemia that is not due to iron depletion (such as thalassemia, refractory anaemia, anaemia due to medullary insufficiency and inflammatory anaemia).

Warnings and precautions
Talk to your doctor or pharmacist before taking TOT'HEMA.

- The prevention of infantile iron 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 intakes in case of a low-sugar diet or diabetes. This medicine is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare hereditary diseases).
- This medicine contains 0.08 g of glucose per ampoule. This should be taken into account in the daily intakes in case 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 the teeth in case of prolonged use (e.g. for 2 weeks or more).
- The medicine contains small amounts of ethanol (alcohol), less than 100 mg per ampoule.

Children
Not applicable.

Other medicines and TOT'HEMA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must wait for at least 2 hours between administration TOT'HEMA and administration one of the following medicines:
- Antibiotics such as cyclines or such as fluoroquinolones (medicines used to treat some infections),
- Diphosphonates (medicines used to treat bone diseases),
- Penicillamine (medicine used to treat rheumatoid arthritis and Wilson's disease),
- Medicines containing thyroxin (medicines used to treat thyroid),
- Local gastrointestinal medicines such as salts, oxides and hydroxides of magnesium, aluminium and calcium.

TOT'HEMA with food and drink
Drinking too much tea inhibits iron absorption. Hence you should avoid taking TOT'HEMA when drinking tea.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Driving and using machines
Not applicable.

TOT'HEMA contains glucose, sucrose and ethanol (see section "Warnings and precautions").

3. How to take TOT'HEMA, oral solution in ampoule

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- **As a curative treatment of iron deficiency and of iron deficiency anaemia:**
  Adults: 100 to 200 mg of elemental iron per day, i.e. 2 to 4 ampoules per day.
  Infants from 1 month and children: 5 to 10 mg of elemental iron/kg/day.

- **As a preventive treatment for iron deficiency:**
  Pregnant women: 50 mg 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
Shake the ampoule before use.
This medicine is taken orally.
Content of ampoule should be diluted in water, sweetened or not, or in 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.

Treatment duration
Treatment must last long enough to cure anaemia and restore iron stocks, which, in 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 iron stocks, to be eventually prolonged if the cause of anaemia is not under control.
Follow 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 of gastro-intestinal necrosis associated with nausea, vomiting and a state of shock, in most cases.
Treatment should be provided as early as possible by pumping stomach using a 1% solution of sodium bicarbonate.
The use of a chelating agent is efficient, the most specific being deferoxamine, mainly when the serum iron concentration is higher than 5 µg/mL. State of shock, dehydration and acido-basic disturbances are treated following the standard practice.

If you forget to take TOT'HEMA
Do not take a double dose to make up for a forgotten dose.

If you stop taking TOT'HEMA
Not applicable.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon side effects (affecting 1 to 10 patients in 1 000):
- Digestive disorders: heartburn, nausea, vomiting, constipation, diarrhoea.
- Usual black-colored stools.
- Brown or black stains on the teeth, stains disappear once treatment is ended. They can also be decreased by teethbrushing.

Side effects with unknown frequency:
- Possible 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 via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (ANSM - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr.

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 this medicine out of the sight and reach of children.

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

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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 colouring agent E150c (glucose, ammonium hydroxide), tutti frutti flavour (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 an oral ampoule.
Each box contains 20 ampoules.

Marketing Authorisation Holder
LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

Manufacturer
INNOTHERA CHOUZY
RUE RENE CHANTEREAU, CHOUZY-SUR-CISSE
41150 VALLOIRE-SUR-CISSE

This medicinal product is authorised in the Member States of the EEA under the following names:
Not applicable.

This leaflet was last revised in December 2018.

Other sources of information
Detailed information on this medicine is available on the ANSM website (France).