NOTICE

ANSM - Last updated: 17/03/2017

Name of the medicinal product

TOPLEXIL 0.33 mg / ml, syrup

oxomemazine

Please read this leaflet carefully before you start taking this medicine because it contains important information for you.

You should always take this medicine by following the instructions in this leaflet or by your doctor or pharmacist.

- Keep this leaflet. You might need to read it again.
- Ask your pharmacist for advice or information.
- If you experience any of the side effects, talk to your doctor, or your pharmacist. This also applies to any side effects not mentioned in this leaflet. See section 4.
- You should contact your doctor if you experience no improvement or feel less well after a few days.

Do not use this medication for children.

What is in this leaflet?

1. What is TOPLEXIL 0.33 mg / ml, syrup and in which cases it is used?
2. What should be known before taking TOPLEXIL 0.33 mg / ml, syrup?
3. How to take TOPLEXIL 0.33 mg / ml, syrup?
4. What are the possible side effects?
5. How to store TOPLEXIL 0.33 mg / ml, syrup?
6. Package contents and other information.

1. WHAT IS TOPLEXIL 0.33 mg / ml, syrup AND WHAT IT IS USED FOR?

Pharmacotherapeutic group - ATC code: R06AD08 (R: Respiratory system).

TOPLEXIL 0.33 mg / ml syrup is a cough suppressant belonging to the family of antihistamines of phenothiazinic neuroleptic type. It is opposed to the effects of histamine especially on the bronchi. It is recommended to calm dry coughs and coughs of irritation in adults and children over 2 years of age, especially when they occur in the evening or at night.

2. BEFORE YOU TAKE TOPLEXIL 0.33 mg / ml, syrup?

If your doctor has told you about an intolerance to some sugars, contact your doctor before taking this medicine.

Do not take TOPLEXIL 0.33 mg / ml, syrup:

- if you are allergic (hypersensitive) to the active substance (oxomemazine) or to any of the other ingredients of this medication mentioned in section 6.
- if you are allergic to a drug of the same family as TOPLEXIL 0.33 mg / ml syrup (antihistamines) used to treat allergies,
- do not give TOPLEXIL 0.33 mg / ml syrup to a child under 2 years of age,
- if you have already had a significant decrease in the level of certain white blood cells (granulocytes) in the blood (agranulocytosis),
- if you have difficulty urinating (disorders of prostatic origin or otherwise),
- if you have a risk of closed-angle glaucoma (high pressure inside the eye that may affect the eyesight),
- if you are taking a medication containing cabergoline or quinagolide (used to control excessive prolactin production) (see section "Other medicines").

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK FOR THE OPINION OF YOUR PHYSICIAN OR YOUR PHARMACIST.
Warnings and Precautions

Take special care with TOPLEXIL 0.33 mg / ml syrup:

Special warnings

· If the cough persists despite the use of TOPLEXIL 0.33 mg / ml syrup, do not increase the doses.

Consult your doctor. Indeed, cough is a symptom that can have various origins: respiratory infections, bronchitis, flu, allergy, asthma, whooping cough, irritation, etc ...

In addition, tobacco use worsens or maintains cough.

· There are 2 types of coughs: dry coughs and greasy coughs. You should not treat an oily cough by using this medicine. Indeed, the fat cough is a natural means of defense necessary for the evacuation of bronchial secretions (mucus).

· If the cough becomes oily with congestion, sputum or fever, seek the advice of your doctor.

· Do not try to treat a fatty cough by combining this drug with a cough medicine.

· You should not expose yourself to sunlight or ultraviolet (UVA) rays during treatment.

· This medication should be used with caution due to the risk of drowsiness.

· Combination with other sedative medicines is not recommended (see section "Other medicines used or taken").

Precautions for use

Before taking this medicine, tell your doctor:

· If you have a chronic bronchial or lung disease with cough and sputum.

· If you have a chronic liver disease (severe hepatic impairment) or kidney (severe renal failure), your doctor will have to adjust the dose to your condition.

· If you have cardiovascular disease.

· If you suffer from epilepsy.

· If you are over 65 years of age (especially if you have chronic constipation, difficulty urinating due to increased prostate volume, hypotension, dizziness, or drowsiness).

· If the child suffers from asthma, gastroesophageal reflux.

During treatment, see your doctor:

If you have fever with or without signs of infection (angina, ...), pallor or sweating.

Contact your doctor before taking TOPLEXIL 0.33 mg / ml, syrup.

Other medicines and TOPLEXIL 0.33 mg / ml, syrup.

This medication contains an antitussive from the family of antihistamines, oxomemazine.

Other medicines contain it. Do not combine them, so as not to exceed the recommended daily dose (see section "Dosage").

You should never take TOPLEXIL 0.33 mg / ml syrup with medicines containing cabergoline or quinagolide (used to curb excessive production of prolactin) (see section "Never take TOPLEXIL 0.33 mg / ml syrup").

You should avoid taking medicines containing alcohol for the duration of the treatment.

You should wait at least 2 hours between taking TOPLEXIL 0.33 mg / ml syrup and taking gastrointestinal, antacid or charcoal dressings (used to relieve digestive disorders).

Many other medications may decrease alertness and cause drowsiness. Their combination with TOPLEXIL 0.33 mg / ml syrup can increase this effect. These include morphine derivatives (used for pain relief, as cough suppressants or for withdrawal from drug abuse), neuroleptics, benzodiazepines (anxiolytics), barbiturates, hypnotics (sleeping pills), antidepressants, sedative antihistamines, certain antihypertensives,
and drugs containing baclofen and thalidomide.

Inform your doctor or pharmacist if you are taking, have recently taken or may take any other medicines.

TOPLEXIL 0.33 mg / ml, syrup with food and beverages and alcohol

You should avoid drinking alcoholic beverages or taking a medication containing alcohol during your treatment.

Pregnancy and breast feeding

**Pregnancy**

This medication SHOULD NOT BE USED, unless otherwise directed by your doctor, during the first trimester of pregnancy.

If you discover that you are pregnant during treatment, consult your doctor promptly: he alone will be able to adapt the treatment to your condition.

In the late pregnancy, abuse of this medication may cause adverse effects in the newborn. Therefore, always seek the advice of your doctor before using it and never exceed the recommended dose and duration of treatment.

**Breastfeeding**

This drug passes into breast milk. Due to its pronounced sedative properties, its intake should be avoided in case of breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or plan a pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

**Sport**

Not applicable.

**Driving and using machines**

This medication may cause drowsiness, especially at the beginning of treatment. It is not recommended to drive a vehicle or use a machine if you feel this effect. The risk of drowsiness is increased if you consume alcoholic beverages, medicines containing alcohol or other sedative drugs (see section "Other medicines and TOPLEXIL 0.33 mg / ml syrup").

TOPLEXIL 0.33 mg / ml, syrup contains sodium and sucrose.

The use of this medication is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase / isomaltase deficiency (rare hereditary diseases).

This medication contains 3.7 g of sucrose per 5 ml and 7.3 g per 10 ml dose, which should be taken into account in the case of a low-sugar diet or diabetes.

This medicine contains sodium. This medicine contains 8.25 mg of sodium per 5 ml of syrup and 16.50 mg of sodium per 10 ml of syrup: to be taken into account in patients controlling their sodium dietary intake.

3. **HOW TO TAKE TOPLEXIL 0.33 mg / ml, syrup?**

This medication is reserved for adults and children over 2 years of age.

Always take this medication exactly as prescribed by your doctor or pharmacist. Check with your doctor or pharmacist if in doubt.

In adults and children over 40 kg (12 years old): The usual dose is 10 ml of syrup per dose, 4 times a day.

For children aged 2 to 12 years: the daily dose depends on the weight of your child:

- Children from 13 to 20 kg (2 to 6 years): the dose is 5 ml of syrup per dose, 2 to 3 times a day.
- Children 20 to 30 kg (6 to 10 years): the dose is 10 ml of syrup per dose, 2 to 3 times a day.
- Children 30 to 40 kg (10 to 12 years): the dose is 10 ml of syrup per dose, 3 to 4 times a day.

**Frequency of Administration**

Receptacles must be renewed only if necessary and spaced at least 4 hours apart.
This medication may cause drowsiness. It is best to take TOPLEXIL 0.33 mg / ml syrup at night.

**Administration mode**

This medication is taken orally. Use the supplied dosing cup in the box.

**Duration of treatment**

Treatment should be short (a few days) and limited to coughing times.

If your cough persists, seek advice from your doctor.

If you take more TOPLEXIL 0.33 mg / ml, syrup you should:

Consult your doctor or doctor immediately.

Overdose in TOPLEXIL 0.33 mg / ml syrup may cause convulsions (especially in children), drowsiness, alertness, coma.

If you forget to take TOPLEXIL 0.33 mg / ml, syrup:

Do not take a double dose to make up for the single dose you have forgotten to take;

If you stop taking TOPLEXIL 0.33 mg / ml, syrup:

Not applicable.

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

4. WHAT ARE POSSIBLE SIDE EFFECTS?

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

**STOP TREATMENT AND IMMEDIATELY CONSULT A DOCTOR**

- If you have signs of allergy to the medication such as:
  - redness on the skin, eczema, purple spots on the skin (purpura),
  - swelling of the face and / or neck may cause difficulty breathing and put you at risk (angioedema)
  - malaise with severe drop in blood pressure (anaphylactic shock).

- If you experience an exaggerated reaction of the skin after exposure to the sun or UV.

- If you have a decrease in the number of certain blood cells: white blood cells (neutropenia, agranulocytosis), platelets (thrombocytopenia) or red blood cells (haemolytic anemia).

The following effects may also occur:

- Drowsiness, decreased vigilance especially at the beginning of treatment.

- Disorders of memory or concentration, dizziness.

- Difficulty coordinating movement, trembling.

- Confusion, hallucinations.

- Dry mouth, visual disturbances, difficulty urinating (urine retention), constipation, palpitations of the heart, significant drop in blood pressure during the transition to the standing position, sometimes responsible for dizziness and / or malaise (orthostatic hypotension).

More rarely, signs of excitement (agitation, nervousness, insomnia) may occur.

**Declaration of side effects**

If you experience any side effects, talk to your doctor or pharmacist. This also applies to any side effects not mentioned in this leaflet. You can also report adverse reactions directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Centers of Pharmacovigilance - Website: www.ansm.sante.fr

By reporting adverse reactions, you are helping to provide more information about the safety of the drug.

5. HOW TO STORE TOPLEXIL 0.33 mg / ml, syrup?
Keep this medicine out of the reach and sight of children.

Store at a temperature not exceeding + 25 °C.

Store in the original package in order to protect from light.

Store at maximum 6 months after first opening the bottle.

Do not use this medicine after the expiry date which is stated on the package.

Do not throw any medicines into drains or rubbish. Ask your pharmacist to remove any medications you are no longer using. These measures will help protect the environment.

6. PACKAGE CONTENTS AND OTHER INFORMATION

What TOPLEXIL contains 0.33 mg / ml, syrup.

· The active substance (s) is (are):

  Oxomemazine ................................................. .................................................. ...................... 0.033 g

· The other component (s) is (are):

  Sodium benzoate, glycerol, citric acid monohydrate, sodium citrate, caramel compound flavor, caramel
  (E150), sucrose solution, purified water.

What is TOPLEXIL 0.33 mg / ml, syrup and contents of the pack

This medication is in the form of a syrup in a 150 ml, 200 ml or 250 ml (brown glass) flask with a measuring
  cup (polypropylene).

Not all pack sizes may be marketed.

Marketing Authorization Holder

SANOFI-AVENTIS FRANCE
82, AVENUE RASPAIL
94250 GENTILLY

Marketing Authorization Operator

SANOFI-AVENTIS FRANCE
82, AVENUE RASPAIL
94250 GENTILLY

Maker

A. NATTERMANN & CIE GMBH
NATTERMANN ALLEE 1
D-50829 COLOGNE

or

FAMAR LYON
AVENUE OF THE GENERAL OF GAULLE
69230 SAINT-GENIS LAVAUX

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

The last date on which this leaflet was revised is:
Other

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