

TUSSINOL-N SYRUP

Brompheniramine Maleate/Phenylephrine Hydrochloride (2mg/5mg per ml)

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What Tussinol-N Syrup is used for

Tussinol-N Syrup can be used for the relief of blocked nose or sinuses, runny nose, itchy watery eyes, cough and sneezing associated with common colds or allergies.

How Tussinol-N Syrup works

Brompheniramine belongs to the group of medications called antihistamines and helps to relieve sneezing and runny nose.

Phenylephrine belongs to the group of medications called nasal decongestants and is used to decrease nasal stuffiness.

Before you use Tussinol-N Syrup

-When you must not use it

Do not use Tussinol-N Syrup if:

- you have had an allergic reaction to brompheniramine, phenylephrine, or any of the other ingredients contained in this medicine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include an itchy skin rash.
- you had an allergic reaction to similar medicines.

Tussinol-N Syrup is not

recommended for children under 2 years of age.

Do not give this medicine to newborn or premature infant.

Pregnancy and Lactation

Tussinol-N Syrup should be used in pregnancy only if the potential benefits to the patient outweighs the possible risk to the fetus.

Tussinol-N Syrup should be used in nursing mothers only if the potential benefits to the patient outweighs the possible risk to the infant.

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking Tussinol-N Syrup.

-Before you start to use it

Inform your doctor in cases of:

- Liver or kidney problems
- Epilepsy
- Severe hyperthyroidism (pathologically excessive production of thyroid hormones)
- Severe ischemic heart disease
- Diabetes mellitus or prostatic hyperplasia [nonmalignant (noncancerous) enlargement of the prostate gland, a common occurrence in older men] should also avoid Phenylephrine.
- Pregnant and breast-feeding mothers
- Had symptoms of anaphylaxis (hypersensitivity induced by preliminary exposure to a substance and usually producing a contraction of smooth muscle and a dilatation of blood vessels) with other “azole” drugs in the past.
- Children below 2 years of age – exercise caution and follow the instruction of doctor or pharmacist when giving to

children between 2 to 6 years of age.

In such cases, please consult your doctor before taking the medicine.

-Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, you should tell your doctor or pharmacist if you are using:

- Central nervous system (CNS) depressants such as alcohol, sedatives, opioid analgesics and hypnotics, may cause an increase sedative effect.
- Monoamine oxidase (MAO) inhibitors and Tricyclic antidepressants (TCAs) may prolong and intensify the anticholinergic and CNS depressive effects.
- Sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants may cause an increase in blood pressure and additive effects.
- Methyl dopa and β - blockers may cause an increase in blood pressure.

How to use Tussinol-N Syrup

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the directions on your prescription bottle, ask your pharmacist, nurse, or doctor to explain the instructions to you.

-How much to use

Adults: 2 teaspoonful (10ml)

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Children: 2-6 years: 1/2
teaspoonful (2.5ml)

6 to 12 years: 1 teaspoonful
(5.0ml)

Do not administer to children age
2-6 years without advice from
your doctor or pharmacist.

-When to use it

To be taken 4-6 hourly or use as
directed by your doctor or
pharmacist.

-How long to use it

Continue taking Tussinol-N Syrup
for as long as your doctor
recommends.

-If you forget to use it

Consult your doctor or pharmacist
on what you should do if you forget
to use it.

Take the missed dose as soon as
you remember. If it is almost time
for your next dose, wait until then
to take the medicine and skip the
missed dose. Do not take a double
dose to make up for the missed
dose.

-If you take too much (overdose)

Contact your doctor immediately
or go to the Emergency
Department of your nearest
hospital, if you think you or
anyone else may have taken too
much of this medicine. Do this
even if there are no signs of
discomfort or poisoning. You
may need urgent medical
attention.

You may get symptoms of
overdose as per:

- Nervousness
- Tremor
- Insomnia
- Agitation
- Irritability

- Abdominal Pain
- Severe Headache
- Nausea
- Vomiting

While you are using Tussinol-N Syrup

-Things you must do

Take your medicine exactly as your
doctor has told you.

Tell all the doctors, dentists and
pharmacists treating you that you
are taking Tussinol-N Syrup.

Tell your doctor immediately if you
became pregnant while taking this
medication.

-Things you must not do

Alcohol drinking.

Do not stop taking the medicine
unless advised by your doctor.

Do not take any new medicines
without consulting your doctor.

Do not give Tussinol-N Syrup to
anyone else, even if they have the
same symptoms or condition as
you

-Things to be careful of

Do not drive a car or operate
machines. Tussinol-N Syrup may
cause drowsiness and may continue
the following day.

Side effects

Like all medicines, Tussinol-N
Syrup can cause side effects,
although not everybody gets them.

Visit your doctor or pharmacist
immediately if you experienced
any side effects after taking this
medicine as the following:

- Sedation
- Impaired performance (impaired
driving performance, poor work
performance, incoordination,
reduced motor skills, and

impaired information
processing); Performance may be
impaired in the absence of
sedation and may persist the
morning after a night-time dose.

- Anxiety
- Hallucinations
- Appetite stimulation
- Muscle dyskinesia [An
impairment in the ability to
control movements,
characterized by spasmodic or
repetitive motions or lack of
coordination]
- Activation of epileptogenic foci
[the area of the cerebral cortex
responsible for causing epileptic
seizures]
- Dryness of the eyes and nose
- Blurred vision
- Urinary hesitancy and retention
- Constipation
- Tachycardia [a rapid heart rate,
especially one above 100 beats
per minute in an adult]

Others: Children and elderly are
more likely to experience adverse
effects such as skin rashes and
urinary retention than other age
groups.

You may experience other side
effects while using Tussinol-N
Syrup. Older children may have
hyperexcitability.

You may report any side effects or
adverse drug reactions directly to
the National Centre for Adverse
Drug Reaction Monitoring by
visiting the website nptra.gov.my
[Consumers → Reporting Side
Effects to Medicines (ConSERF)
or Vaccines (AEFI)].

Storage and Disposal of Tussinol-N Syrup

-Storage

Keep container tightly closed in a
dry place, below 30°C. Protect
from light.

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Do not use this medication after the expiry date which is printed on the product packaging.

Date of Revision

23/5/2023

Serial Number

NPRA(R4/1)110719/00187

-Disposal

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.

Product Description

-What it looks like

Clear, mobile liquid, free from visible impurities. Colour: Green.

-Ingredients

-Active ingredient:

Each 5ml contains
Brompheniramine Maleate 2mg
and Phenylephrine Hydrochloride 5mg.

-Inactive ingredient:

- Liquid Sorbitol 70% (non-crystalline)
- Glycerine (Glycerol)
- Sodium Benzoate
- Disodium Edetate
- Sodium Citrate
- Anhydrous Citric Acid
- Saccharin Sodium (Soluble)
- Colour FDC Green No.3
- Soluble Essence of Grape
- Purified Water
- Sodium Hydroxide

-MAL number

MAL19910130AZ

Product Registration Holder & Manufacturer

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