Summary of Product Characteristics

Tonsilgon® N oral drops, solution

1. NAME OF THE MEDICINAL PRODUCT

Tonsilgon® N

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g oral drops contain:
extract (1:38) from 2,6 g mixture of :

dandelion herb (Taraxaci herba), hostail herb (Equiseti hreba), marshmallow root (Althaeae radix), matricaria flower (Matricariae flos), oak bark (Quercus Cortex), walnut leaves (Jiuglandis folium), yarrow herb (Millefolii herba) (4:5:4:3:2:4:4);
1. extraction agent: ethanol 59% (V/V), 2.-4. extraction agent: purified water
The medicinal product contains 19 % (V/V) alcohol.

For excipients see section 6.1.

3. PHARMACEUTICAL FORM

Oral drops for oral use.
Clear to slightly turbid, yellowish-brown liquid with an odor and taste of chamomile.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Severe and chronic illnesses of the upper respiratory tract (tonsillitis, pharyngitis, laryngitis)
- Prevention of complications arising from viral respiratory infections and as a supplement to antibiotic therapy for bacterial infections

4.2 Posology and method of administration

When the development of symptoms is severe:
Adults and adolescents from 12 years should take 25 drops, 5-6 times a day.
Children from 6-11 years should take 15 drops, 5-6 times a day
Children from 1-5 years should take 10 drops, 5-6 times a day
After the symptoms have become less severe, treatment with Tonsilgon® N should continue for 1 more week.
When the severe symptoms of illness have disappeared:
Adults and adolescents from 12 years should take 25 drops, 3 times a day.
Children from 6-11 years should take 15 drops, 3 times a day.
Children from 1-5 years should take 10 drops, 3 times a day.
Drops should be taken undiluted. Keep them in the mouth for a short time before swallowing.

If needed, drops may be diluted with some liquid (e.g. a glass of water).

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients of the medicinal product
- Known allergy to plants of the Compositae family.

4.4 Special warnings and special precautions for use

The use in children under 1 year of age is not recommended.
This medicinal product contains 19 vol % alcohol.
The product should not be taken by patients suffering from alcoholism nor after successful treatment for alcoholism. The alcohol content should be taken into account in high-risk groups such as patients with liver disease, epilepsy, brain disease.

4.5 Interactions with other medicaments and other forms of interaction

Interactions with other medicines are not known.
When using preparations which contain oak bark, the resorption of alkaloids and other alkaline medicinal agents may be reduced or blocked.

4.6. Pregnancy and lactation

Since there is no sufficient experience of the use during pregnancy and lactation, the medicinal product should be administered during pregnancy and lactation only after strict risk-benefit evaluation by the attending physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Like all medicines, Tonsilgon N oral drops can cause side effects.

The following categories are used for the frequencies of side effects:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1.000 to < 1/100)
Rare (≥ 1/10.000 to < 1/1.000)
Very rare (<1/10.000)
Not known (frequency cannot be estimated from the available data)

Gastrointestinal disorders
Uncommon: Gastrointestinal disorders

Immune system disorders
Not known: Allergic reactions

In association with preparations containing matricaria flowers hypersensitivity reactions may occur, also in people with hypersensitivity to other plants of the Compositae family (e.g. mugwort, yarrow, chrysanthemum, marguerite) due to so-called cross reactions.

At the first signs of a hypersensitivity / allergic reaction Tonsilgon N oral drops must not be taken again.

4.9. Overdose

No case of overdose has been reported.
Treatment of overdose:
In case of overdose, symptomatic treatment should be initiated.

5. PHARMACOLOGICAL PROPERTIES

ATC code: R02AA20

5.1 Pharmacodynamic properties

Polysaccharides derived from chamomile and marshmallow stimulate the non-specific immune response by increasing macrophage and granulocyte phagocytosis. These active substances also increase the intracellular destruction of phagocytosed bacteria through intensified formation of bactericidal acting oxygen metabolites. Horsetail contributes to these effects with its known curative and prophylactic properties. Polysaccharides, essential oils, and flavonoides (chamomile, marshmallow, yarrow) relieve the symptoms of the mucous membranes during respiratory tract infections. In vitro studies on the tannin-rich oak bark in Tonsilgon® N demonstrate antiviral effects including effects against influenza viruses.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There is no knowledge of toxicological properties neither for the finished drug nor for the individual drugs.
In a genotoxicity test (*Salmonella typhimurium* bacterial reverse mutation assay) with the active ingredients of Tonsilgon no mutagenic potential of the combination could be observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Slight turbidity or flocculation may occur during storage. The activity of the preparation is not affected by this. Once opened, the bottle should be used for 6 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Tonsilgon® Noral drops are available in bottles with dropper applicator, packaged in folding carton.
The following packaging sizes are available: 50 ml and 100 ml.
Not all pack sizes may be marketed.

6.6 Instruction for use/handling

Not applicable.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

71256.00.00

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

27.07.2012

10. DATE OF (PARTIAL) REVISION OF THE TEXT

February 2015