

Patient Information Leaflet

(a) Active Ingredients

Each 5ml of Mucosolvan Liquid contains ambroxol hydrochloride 30mg.

(b) Inactive Ingredients

Mucosolvan Liquid also contains hydroxyethylcellulose, benzoic acid, sucralose, strawberry cream aroma, vanillaflavour and water purified.

(c) What Mucosolvan is used for

Mucosolvan is used in conditions where there are a lot of thick secretions or mucus in your air passages.

Mucosolvan contains ambroxol hydrochloride, which helps to clear the chest by thinning the mucus in your air passage.

(d) Taking Mucosolvan

The recommended dose for adults and children are stated below:

Adult and children over 12 years:
10ml 2 times daily.

For children under 12 years the following dosage regimen is recommended depending on severity of the disease.

Children 6-12 years:
5ml 2-3 times daily.

Children 2-5 years:
2.5 ml 3 times daily.

Mucosolvan can be taken with or without food.

Mucosolvan is not recommended for children under 2 years of age without medical advice.

The use of Mucosolvan without medical supervision is not intended in patients who suffer from such condition chronically.

Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of treatment with Mucosolvan.

(e) Warnings

- **When you must not take Mucosolvan**

Do not use Mucosolvan if you are allergic to ambroxol hydrochloride or to any of the other ingredients in Mucosolvan.

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

You should not use Mucosolvan after the EXPIRY DATE on the carton or container.

In very few cases, severe skin disorders such as Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN) have been reported after administration of mucolytic substances (e.g. ambroxol hydrochloride), which in most cases could be explained by the patient's underlying disease and/or the concomitant medication. In addition

during the early phase of a Steven-Johnson Syndrome or TEN a patient may first experience non-specific influenza-like prodromes (e.g. fever, aching body, rhinitis, cough and sore throat). It is possible that a symptomatic treatment is started with a cough and cold preparation due to these misleading non-specific influenza-like prodromes. Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

In the presence of impaired renal function a physician must be consulted.

- **Before you start to take Mucosolvan**

Before taking Mucosolvan, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Liver problems,
- Kidney problems.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

Before using Mucosolvan, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

Mucosolvan may increase the amount of antibiotic

penetration. Antibiotics are medicines used to treat infections.

- **Side effects**

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Mucosolvan.

Occasional, mild side effects from Mucosolvan include:

- Nausea,
- Diarrhoea,
- Dyspepsia (e.g. indigestion, bloated feeling)
- Vomiting
- Abdominal pain
- Heartburn
- A feeling of fullness in the stomach (a bloated feeling).
- Dysgeusia (e.g. changed taste)
- Oral and pharyngeal hypoaesthesia
- Dry mouth
- Dry throat

Hypersensitivity has occurred with the use of Mucosolvan. Symptoms of hypersensitivity may include:

- Rash
- Pruritus
- Urticaria
- Anaphylactic shock
- Angioedema

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Mucosolvan, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Mucosolvan.

- **Pregnancy**

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

The use of Mucosolvan in the first trimester is not recommended.

- **Breastfeeding**

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Ambroxol hydrochloride is excreted in breast milk.

Mucosolvan is not recommended for use in nursing mothers.

The benefits of Mucosolvan must be assessed against possible effects on your child.

- **Fertility**

Nonclinical studies do not indicate direct or indirect harmful effects with respect to fertility.

- **If you have taken too much Mucosolvan**

Seek medical advice if you have taken more than the recommended or prescribed dose of Mucosolvan.

Advice can be provided by a doctor or pharmacist.

- **Effects on ability to drive and use machines**

There is no evidence from postmarketing data for an effect on the ability to drive and use machines. Studies on the effects on the ability to drive and use machines have not been performed

(f) Storage condition

Mucosolvan should be kept in a dry place where the temperature stays below 30°C.

Keep out of the reach of children.

Please refer to packaging for information on shelf-life

Manufactured by
Delpharm Reims
Reims, France

Product Registrant
sanofi-aventis Singapore
Pte Ltd
38 Beach Road #18-11
Singapore 189767

Revision date: June 2018



30mg Tablets

ambroxol hydrochloride

Patient Information Leaflet

(a) Active Ingredients

Each Mucosolvan tablet contains ambroxol hydrochloride 30mg.

(b) Inactive Ingredients

Mucosolvan tablet also contains lactose, maize starch dried, silica colloidal anhydrous and magnesium stearate.

(c) What Mucosolvan is used for

Mucosolvan is used in conditions where there are a lot of thick secretions or mucus in your air passages.

Mucosolvan contains ambroxol hydrochloride, which helps to clear the chest by thinning the mucus in your air passage.

(d) Taking Mucosolvan

The recommended dose for adults is 1 tablet 3 times daily.

For better effect, you may administer 2 tablets 2 times daily. The tablets should be taken with liquid. Mucosolvan can be taken with or without food.

Mucosolvan liquid formulation is available for children.

Mucosolvan is not recommended for children under 2 years of age without medical advice.

The use of Mucosolvan without medical supervision is not intended in patients who suffer from such condition chronically.

Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of treatment with Mucosolvan.

(e) Warnings

- **When you must not take Mucosolvan**

Do not use Mucosolvan if you are allergic to ambroxol hydrochloride or to any of the other ingredients in Mucosolvan.

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

You should not use Mucosolvan after the EXPIRY DATE on the carton or container.

Mucosolvan Tablet contains lactose. If you have rare hereditary galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take this medicine.

In very few cases, severe skin disorders such as Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN) have been reported after administration of mucolytic substances (e.g. ambroxol hydrochloride), which in most cases could be explained by the patient's underlying disease and/or the concomitant medication. In addition during the early phase of a Steven-Johnson Syndrome or TEN a patient may first experience non-specific influenza-like prodromes (e.g. fever, aching body, rhinitis, cough and sore throat). It is possible that a



symptomatic treatment is started with a cough and cold preparation due to these misleading non-specific influenza-like prodromes. Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

In the presence of impaired renal function a physician must be consulted.

- **Before you start to take Mucosolvan**

Before taking Mucosolvan, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Liver problems,
- Kidney problems.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

Before using Mucosolvan, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

Mucosolvan may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

- **Side-effects**

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Mucosolvan.

Occasional, mild side effects from Mucosolvan Tablet include:

- Nausea,
- Diarrhoea,
- Dyspepsia (e.g. indigestion, bloated feeling)
- Vomiting
- Abdominal pain
- Heartburn
- A feeling of fullness in the stomach (a bloated feeling).

Hypersensitivity has occurred with the use of Mucosolvan. Symptoms of hypersensitivity may include:

- Rash
- Pruritus
- Urticaria
- Anaphylactic shock
- Angioedema

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Mucosolvan, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Mucosolvan.

- **Pregnancy**

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

The use of Mucosolvan in the first trimester is not recommended.

- **Breastfeeding**

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Ambroxol hydrochloride is excreted in breast milk.

Mucosolvan is not recommended for use in nursing mothers.

The benefits of Mucosolvan must be assessed against possible effects on your child.

- **Fertility**

Nonclinical studies do not indicate direct or indirect harmful effects with respect to fertility.

- **If you have taken too much Mucosolvan**

Seek medical advice if you have taken more than the recommended or prescribed dose of Mucosolvan.

Advice can be provided by a doctor or pharmacist.

- **Effects on ability to drive and use machines**

There is no evidence from postmarketing data for an effect on the ability to drive and use machines. Studies on the effects on the ability to drive and use machines have not been performed

(f) Storage condition

Mucosolvan should be kept in a dry place where the temperature stays below 30°C.

- **Keep out of the reach of children.**

Please refer to packaging for information on shelf-life

Manufactured by
PT. Boehringer Ingelheim
Indonesia
Jl Lawang Gintung No 89
Bogor 16133
Indonesia

Product Registrant
sanofi-aventis Singapore Pte Ltd
38 Beach Road #18-11
Singapore 189767

Revision date: June 2018

Patient Information Leaflet

(a) Active Ingredients

Each Mucosolvan 24 Hours contains ambroxol hydrochloride 75mg.

(b) Inactive Ingredients

Mucosolvan 24 Hours also contains crospovidone collidon CL, carnauba wax, stearyl alcohol, magnesium stearate.

(c) What Mucosolvan is used for

Mucosolvan is used in conditions where there are a lot of thick secretion or mucus in your air passages.

Mucosolvan contains ambroxol hydrochloride, which helps to clear the chest by thinning the mucus in your air passage.

(d) Taking Mucosolvan

The recommended dose for adults is 1 capsule once daily.

The capsules should not be opened or chewed, but swallowed whole with ample liquid. Mucosolvan can be taken with or without food.

The use of Mucosolvan without medical supervision is not intended in patients who suffer from such condition chronically. Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of treatment with Mucosolvan.

(e) Warnings

• **When you must not take Mucosolvan**

Do not use Mucosolvan if you are allergic to ambroxol or to any of the other ingredients in Mucosolvan.

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

You should not use Mucosolvan after the EXPIRY DATE on the carton or container.

In very few cases, severe skin disorders such as Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN) have been reported after administration of expectorants (e.g. ambroxol hydrochloride), which in most cases could be explained by the patient's underlying disease and/or the concomitant medication. In addition during the early phase of a Steven-Johnson Syndrome or TEN a patient may first experience non-specific influenza-like prodromes (e.g. fever, aching body, rhinitis, cough and sore throat). Mislead by these non-specific influenza-like prodromes it is possible that a symptomatic treatment is started with a cough and cold preparation. Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

In the presence of impaired renal function MUCOSOLVAN® may be used only after consulting a physician.

• **Before you start to take Mucosolvan**

Before taking Mucosolvan, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Liver problems,
- Kidney problems.

Before using Mucosolvan, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

Mucosolvan may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

• **Side-effects**

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Mucosolvan.

Occasional, mild side effects from Mucosolvan 24 Hours include:

- Nausea,
- Diarrhoea,
- Dyspepsia (e.g. indigestion, bloated feeling)
- Vomiting
- Abdominal pain
- Heartburn
- A feeling of fullness in the stomach (a bloated feeling).

Hypersensitivity reactions have occurred with the use of Mucosolvan. Symptoms of hypersensitivity may include:

- Rash
- Pruritus
- Urticaria
- Anaphylactic shock
- Angioedema

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Mucosolvan, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Mucosolvan.

- **Pregnancy**

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

The use of Mucosolvan in the first trimester is not recommended.

- **Breastfeeding**

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Ambroxol hydrochloride is excreted in breast milk. Mucosolvan is not recommended for use in nursing mothers.

The benefits of Mucosolvan must be assessed against possible effects on your child.

- **Fertility**

There are no direct or indirect indication harmful effects with respect to fertility.

- **If you have taken too much Mucosolvan**

Seek medical advice if you have taken more than the recommended or prescribed dose of Mucosolvan.

Advice can be provided by a doctor or pharmacist.

- **Effects on ability to drive and use machines**

There is no evidence from postmarketing data for an effect on the ability to drive and use machines. Studies on the effects on the ability to drive and use machines have not been performed.

(f) Storage condition

Mucosolvan should be kept in a dry place where the temperature stays below 30°C.

- **Keep out of the reach of children.**

Please refer to packaging for information on shelf-life

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Boehringer Ingelheim Pharma
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