

PATIENT INFORMATION LEAFLET
Information for the Patient about
IVYFILM

Read all of this leaflet carefully before you start using IVYFILM, because it contains important information for you.

This medicine is available without a doctor's prescription. Nevertheless you still need to use IVYFILM carefully to get the best results from it.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **You must see a doctor if your symptoms worsen or do not improve.**
- **Do not share IVYFILM with any other person.**
- **This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.**

SCHEDULING STATUS:

SO

PROPRIETARY NAME (AND DOSAGE FORM):
IVYFILM (Orodispersible Thin Film).

CATEGORY AND CLASS:

D 10.1 Antitussives and expectorants
Complementary Medicine: Western Herbal

WHAT IVYFILM CONTAINS:

Each orodispersible thin film contains:

Ingredient	Quantity (mg per thin film)
Dried extract from Ivy leaves (<i>Hedera helix</i> L., folium); (DER 4-8:1, extraction solvent 30 % (m/m) ethanol)	16,0 mg

Other inactive ingredients include blansone 7LF, fruit punch flavour, glycerol, pullulan, sodium copper chlorophyllin, sucralose and titanium dioxide.

IVYFILM is free from alcohol, aspartame, caffeine, preservatives, tartrazine and yeast.
Contains sweetener (sucralose)

WHAT IVYFILM IS USED FOR:

IVYFILM is a traditional herbal preparation used as an expectorant for the relief of productive cough in adults and children over the age of 2 years.

BEFORE YOU TAKE IVYFILM:

Do NOT take IVYFILM:

- If you are allergic (hypersensitive) to any of the active or inactive ingredients in the formulation.
- If you are allergic to members of the Araliaceae family of flowering plants.
- If you are pregnant or breastfeeding your baby (see "**Pregnancy and breastfeeding**").
- The use of IVYFILM in children under the age of 2 years is not recommended.

Take special care with IVYFILM:

- If you are already taking a medicine to help stop your coughing such as codeine or dextromethorphan.
- If you suffer from gastritis (inflammation of the lining of

the stomach) or gastric ulcer (stomach ulcer).

- Consult your doctor, pharmacist or other healthcare professional if you have difficulty with breathing, have a fever or bloody phlegm.
- **Children between 2 and 4 years of age: Persistent or recurrent cough requires medical diagnosis before treatment.**

Consult your doctor prior to using IVYFILM if any of the above precautions are applicable to you.

IVYFILM should not be used to replace any medicines prescribed by your doctor.

Consult your doctor if you are taking prescription medicines (see "**Taking IVYFILM with other medicines**").

DO NOT TAKE any other nutritional or herbal supplements without first discussing their combined use with IVYFILM with your doctor or pharmacist (see "**Taking IVYFILM with other medicines**").

Ensure that you stay within the recommended dosage guidelines.

Use in children:

IVYFILM should not be taken by or given to children under the age of 2 years, as safety and efficacy have not been established.

Taking IVYFILM with food and drink:

IVYFILM can be taken with or without food.

IVYFILM should be taken without water.

Pregnancy and breastfeeding:

Do NOT take IVYFILM while you are pregnant or breastfeeding your baby as safety has not been established (see "**Do NOT take IVYFILM**").

If you are pregnant or breastfeeding your baby while taking IVYFILM, please consult your doctor or pharmacist or other healthcare professional for advice. Avoid use of IVYFILM during pregnancy and breastfeeding.

Driving or using machinery:

It is unlikely that IVYFILM will affect your ability to drive or operate machinery.

Taking IVYFILM with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of IVYFILM with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please discuss the use of the following medicines or substances in combination with IVYFILM with your doctor or pharmacist:

- Cough suppressants (antitussives), such as codeine or dextromethorphan, as the combined use with IVYFILM is not recommended.

HOW TO TAKE IVYFILM:

Children 2 - 5 years of age:

One film up to two times daily; maximum daily dose 32 mg (two films).

Adults and children over 6 years:

1 film up to three times daily; maximum daily dose 48 mg (three films).

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Method of administration:

- Remove the orodispersible film from the individual sachet without damaging the film as follows:
Open the sachet at the tear tag and slowly tear it off.
- Do not cut the sachet.
- Place IVYFILM on the tongue (make sure your mouth is empty and your fingers are dry).
- IVYFILM should disintegrate on your tongue within a short time and can subsequently be swallowed with saliva.
- For the use in smaller children the orodispersible film can be folded into a smaller size before placing it on the tongue.

Consult your doctor if symptoms persist for longer than 7 days or return after the use of IVYFILM.

If you have the impression that the effect of IVYFILM is too strong or too weak, please speak to your doctor or pharmacist.

If you take more IVYFILM than you should:

If you take more IVYFILM than you should, you may experience an increase in the side-effects listed below (see "POSSIBLE SIDE-EFFECTS").

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

If you forget to take IVYFILM:

Always take IVYFILM as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

IVYFILM may have side-effects.

Not all side-effects reported for IVYFILM are included in this leaflet. Should your general health worsen while taking IVYFILM, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking IVYFILM, and consult your doctor, pharmacist or healthcare professional if you experience any of the following signs and symptoms.

- Side-effects that can occur frequently:
 - Gastrointestinal disorders, including nausea, vomiting or diarrhoea (loose stools).
- Side-effects that can occur less frequently:
 - Allergic (hypersensitive) reactions, including urticaria (hives), skin rash, couperosis (redness or red spots in the face due to the presence of small, dilated red blood vessels) and dyspnoea (shortness of breath).

Please inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF IVYFILM:

Store at or below 25 °C in a dry place.

Keep the sachets tightly closed to protect from moisture.

Keep the films in the outer carton until required for use.

Do not take the films after the expiry date stated on the package.

Return all unused films to your pharmacist.

Do not dispose of unused films in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF IVYFILM:

Orodispersible thin film, individually packed in a sealed sachet. Sachets are packed in an outer carton containing 30 sachets.

IDENTIFICATION OF IVYFILM:

Dark green coloured orodispersible thin film with a fruit punch flavour.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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