

## 6.2 What Ardeyhepan® looks like and contents of the pack

### Appearance

Light-green/ round coated tablets

### Packs

Ardeyhepan® is available in the following packs:

- 20 coated tablets
- 50 coated tablets
- 100 coated tablets

## 6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstraße 20, 58313 Herdecke, Germany  
Phone: +49 - 23 30 - 977 677, Fax: +49 - 23 30 - 977 697

**This leaflet was last approved in July 2015**

### Dear Patient!

**It is possible that the leaflet in your medicine pack may differ from this version. This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.**

## Package leaflet: Information for the user

# Ardeyhepan®



### Coated tablets

**For use in adolescents and adults**

**Active substance: Dry extract of milk thistle fruits**

**Read all of this leaflet carefully because it contains important information for you. This medicinal product is available without prescription. However, you still need to take Ardeyhepan® carefully to get the best results from it.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What Ardeyhepan® is and what it is used for
2. Before you take Ardeyhepan®
3. How to take Ardeyhepan®
4. Possible side effects
5. How to store Ardeyhepan®
6. Further information

## 1. What Ardeyhepan® is and what it is used for

**1.1** Ardeyhepan® is a herbal remedy for liver diseases.

**1.2** For supportive treatment of chronic-inflammatory liver diseases, hepatic cirrhosis and toxic (caused by hepatotoxic agents) liver diseases.

## 2. Before you take Ardeyhepan®

### 2.1 Do not take Ardeyhepan®

- If you are hypersensitive to milk thistle fruits and/ or other composite plants or any of the excipients of Ardeyhepan®.
- If you are pregnant

### 2.2 Take special care with Ardeyhepan®

- Ardeyhepan® is not intended for the use of acute intoxications.
- The drug therapy does not compensate for failing to avoid the causes of liver damage, e.g. alcohol
- In case of jaundice (light to intense colour change of the skin to yellow, yellow colouring of the white of the eyes) a doctor should be consulted

### Children

There is not sufficient information with Ardeyhepan® in children. It therefore should not be used in children under the age of 12 years.

## 2.3 Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no interactions with other medicines known.

## 2.4 Pregnancy and breast-feeding

Ardeyhepan® should not be used during pregnancy.

Due to insufficient information, Ardeyhepan® should not be used during lactation.

## 2.5 Driving and using machines

No special precautions are necessary.

## 2.6 Important information about some of the ingredients of Ardeyhepan®

This medicinal product contains lactose and sucrose. If you know that you have an intolerance to some sugars, contact your doctor before taking Ardeyhepan®.

## 3. How to take Ardeyhepan®

Always take Ardeyhepan® exactly as your doctor has told. You should check with your doctor or pharmacist if you are not sure.

### 3.1 Dosage

Unless otherwise prescribed by the doctor, the usual dose is:

Adults and children from the age of 12 years take 1–2 coated tablets 2 times daily (dry extract of milk thistle fruits corresponding to 210–420 mg silymarin).

### 3.2 Method of administration

Ardeyhepan® should be used with a sufficient amount of liquid.

### 3.3 Duration of treatment

The treatment duration is decided by your doctor. If the symptoms persist during the use of Ardeyhepan® you should consult the doctor.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Ardeyhepan® being too strong or too weak.

### 3.4 If you take more Ardeyhepan® than you should

Intoxications have not been reported so far. In case of overdosage the below mentioned side effects may occur to an increased extent. If you have taken more Ardeyhepan® than recommended, you should tell your doctor.

### 3.5 If you forget to take Ardeyhepan®

Do not take a double dose to make up for a forgotten dose. Taking of Ardeyhepan® should be continued as prescribed by your doctor or described in this package leaflet.

### 3.6 If you stop taking Ardeyhepan®

You can stop or discontinue taking Ardeyhepan® at any time, no special precautions are necessary.

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

## 4. Possible side effects

Like all medicines, Ardeyhepan® can cause side effects, although not everybody gets them.

For the assessment of side effects, the following data on frequency are used as a basis:

<b>Very common:</b>	<b>More than 1 of 10 patients treated</b>
<b>Common:</b>	<b>Less than 1 of 10, but more than 1 of 100 patients treated</b>
<b>Uncommon:</b>	<b>Less than 1 of 100, but more than 1 of 1,000 patients treated</b>
<b>Rare:</b>	<b>Less than 1 of 1,000, but more than 1 of 10,000 patients treated</b>
<b>Very rare:</b>	<b>Less than 1 of 10,000 patients treated, or unknown</b>

### 4.1 Possible side effects

Rarely, gastrointestinal complaints, e. g. a slight laxative effect are observed.

Very rarely, hypersensitive reactions, e. g. skin rash or shortness of breath may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

### 4.2 Actions to be taken in case of side effects

If you notice one of the above-mentioned side effects, inform a doctor so that he can decide on the degree of severity and any treatment measures which might be required.

### 4.3 Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ardeyhepan®

Keep out of the reach and sight of children.

Do not use Ardeyhepan® after the expiry date which is stated on the outer carton and on the blister.

### Storage conditions:

Do not store above 25 °C!

## 6. Further Information

### 6.1 What Ardeyhepan® contains

The active substance is: Dry extract of milk thistle fruits.

1 coated tablet contains:

Dry extract of milk thistle fruits (20 – 35:1) corresponding to 105 mg silymarin (calculated as silibinin, HPLC) 162.5 – 250 mg

Extraction solvent: Ethyl acetate

### The other ingredients are:

Lactose monohydrate, Crospovidone, Microcrystalline cellulose, Cellulose powder, Colloidal silica, Sodium starch glycolate (type A), Stearic acid (Ph. Eur.), Magnesium stearate (Ph. Eur.), Eudragit E (Basic butylated methacrylate copolymer), Sucrose, Talc, Calcium carbonate, Arabic gum, Tragacanth, Quinoline yellow (E 104), Indigo carmine (E 132), Titanium dioxide (E 171), Montan glycol wax, Castor oil, Glucose syrup, dried

For diabetics, taking 1 coated tablet Ardeyhepan® should be calculated as 0.02 carbohydrate exchange units.