### Patient Information Leaflet HARUFEN Plaster

(Ketoprofen)

#### Read this Patient Information carefully before you start using HARUFEN plaster because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- HARUFEN plaster is General Sales List medicine. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this information.

#### What is in this leaflet:

- 1. What HARUFEN is and what it is used for
- 2. What you need to know before you use HARUFEN
- 3. How to use HARUFEN
- 4. Possible side effects
- 5. How to store HARUFEN
- 6. Contents of the pack and other information.

#### 1. What HARUFEN is and what it is used for

HARUFEN contains ketoprofen, a non-steroidal anti-inflammatory drug which works by reducing the pain in your skin.

HARUFEN is used for relief of pain and inflammation of the following diseases or symptoms:

- Arthritis deformans.
- Periarthritis of shoulder.
- Tendonitis.
- Peritendinitis.
- Humeral epicondylitis (tennis elbow etc.).
- Muscle pain.
- Swelling and posttraumatic swelling and pain.

# 2. What you need to know before you use HARUFEN

Do not us HARUFEN plaster if you:

- Are allergic to ketoprofen or any of the other ingredients in HARUFEN plaster (listed in section 6).
- Have patients who have and have had aspirin-induced asthma or asthma attack caused by other non-steroidal anti-inflammatory drugs (NSAIDs).

#### Warnings and precautions

Tell your doctor or pharmacist before using HARUFEN, if you have bronchial asthma (asthma attacks may occur) and you are continuously receiving medical treatment for a chronic disease.

#### Other medicines and HARUFEN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. HARUFEN should not be used in pregnancy unless clearly necessary.

Safety has not been established. Avoid long-term use on large areas or mass amounts.

#### 3. How to use HARUFEN

Adults:

Apply on plaster to the affected area after removal of release paper twice daily

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you still have a lot of pain after use of HARUFEN, tell your doctor. Your doctor will check how well HARUFEN is working at regular intervals.

#### Before you stick HARUFEN on the affected area

If you have had a recent bath or shower, you should wait until your skin cools before using the plaster.

#### Sticking the plaster on

Step 1: Open the pouch and take plasters out Tear open or cut the pouch along the cutting line. When using scissors, be careful no to damage the Plasters. Take out one plaster.

## Step 2: Remove the middle zigzag release paper from the plaster.

A protective liner covers the sticky (adhesive) side of the plaster. Peel off middle zigzag release paper from the plaster. Do not touch the sticky part of the plaster with your fingers.

### Step 3: Apply the plaster and press it firmly onto the skin

Apply the sticky side of the plaster onto your chosen skin side.

# Step 4: Remove the remaining sides of the release paper

Peel off the remaining sides of the release paper and stretch the plaster as needed for a smooth and even plaster application. Press down the plaster firmly to make sure that the edges stick well.

#### Removing the HARUFEN plaster

Gently pull on 1 edge of the HARUFEN plaster to remove it off your skin. Fold the HARUFEN plaster in half and throw the used HARUFEN plaster in the trash out of the reach of children and pets. Wash your hands with soap and water right away.

#### Bathing, showering and swimming

If at all possible contact with water should be avoided whilst using HARUFEN. Bathing, showering or swimming can be done in the time period when you are not wearing the plaster. If you took a recent bath or shower, you should wait until your skin cools before using the plaster.

#### How to remove HARUFEN

When changing the plaster, remove the old plaster slowly. If it does not come off easily, you can soak it in warm water for a few minutes before removing the plaster.

#### If you use more plasters than you should

If you use more plasters than necessary or wear them for too long, this may increase the risk of getting side effects.

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

#### 4. Possible side effects

Rarely shock, anaphylactic-like reactions (hypersensitivity-like symptoms such as urticaria, difficulty breathing or swelling of the face) may occur.

Asthma attacks may appear within hours after using HARUFEN plaster. Discontinue the use if initial symptoms such as dry rales, wheezing, difficulty breathing occur. Skin: Sometimes dermatitis such as redness, rash, itching, blister, erosion, irritation and

swelling, skin dryness, and pigmentation may occur. By direct sunlight (UV) photosensitivity may occur and expand to the whole body.

#### 5. How to store HARUFEN plaster

Keep this medicine out of the sight and reach of children.

Do not use HARUFEN plaster after the expiry date which is stated on the pouch and on the carton.

Do not refrigerate or freeze.

Do not use HARUFEN plaster if you notice that the pouch has been damaged. Store at or below 30°C in a light resistant tightly closed container.

#### How to throw away HARUFEN plaster

Used plasters still contain active ingredient, which may be harmful to others. Fold the used plasters in half and throw them in the trash so that they are out of the reach of children. Do not throw away any medicine via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What HARUFEN contains

The active substance is ketoprofen. Each plaster contains 30 mg ketoprofen. The other ingredients in the plaster are: Acrylic adhesive solution (Toluene, Isopropyl alcohol, Ethyl acetate, Acrylic copolymer), Rubber adhesive solution (Toluene, Heptane, Hydrocarbon Resin, Polyisobutene), Non woven fabric and release paper.

## What HARUFEN looks like and contents of the pack

Plaster spraying colorless, translucent adhesive to a flesh-colored non-woven fabric and covered with a release paper.

Pack sizes: 7 plasters/pouch x 20's, 7 plasters/pouch x 50's and 10 plasters/pouch x 15's. Not all pack sizes may be marketed.

#### Manufacturer

Sinil Pharmaceutical Co.,Ltd. 28, Boksanggol-gil, Angseong-myeon, Chungju-si, Chungcheongbuk-do, Republic of Korea

## This medicinal product is authorized in the countries under the following names:

Republic of Korea: Harufen plaster

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