

**PATIENT INFORMATION LEAFLET
CORILIEF® 5 FLU TABLET**

Read all of this leaflet carefully before taking this medication

- Keep this leaflet as you may need to read it again
- If you still have questions after reading this leaflet, ask your doctor, health care provider or pharmacist
- This medicine has been indicated for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet you will find information on:

- a. What is Corilief® 5 Flu and what is it used for?
- b. Before you take Corilief® 5 Flu tablet
- c. How to take Corilief® 5 Flu tablet
- d. Possible side effects
- e. How to store Corilief® 5 Flu tablet
- f. Further information

a. What is Corilief® 5 Flu and what is it used for?

Corilief® 5 Flu contains the active ingredients Paracetamol, Diphenhydramine and Pseudoephedrine. It is used for the relief of symptoms associated with colds and flu; including relief of nasal congestion and congestion of mucous membranes of the upper respiratory tract, sneezing, runny nose, coughing, fever, headache, muscular aches and pains. Corilief® 5 Flu tablet is **not recommended for children under 10 years old**.

b. Before you take Corilief® 5 Flu tablets

Do not take Corilief® 5 Flu tablets

If you have known hypersensitivity to Diphenhydramine, Paracetamol, Pseudoephedrine or any of the excipients (see **What Corilief® 5 Flu tablets contains**)

Take special care with Corilief® 5 Flu tablet:

Diphenhydramine and **pseudoephedrine** are known to cause central nervous system adverse events. Here's a simplified version of the instructions:

Stop taking Corilief® 5 Flu Tablets if you experience:

- Hallucinations
- Restlessness
- Sleep disturbances

Use with caution if you have:

- Enlarged prostate
- Difficulty urinating
- Risk of glaucoma
- Kidney problems
- Liver disease
- Blood vessel problems

Increased risk of overdose for those with liver disease caused by alcohol use.

May cause drowsiness; do not use to make a child sleepy.

Important advice on the label:

- Seek medical help immediately if you overdose, due to the risk of serious liver damage.
- Do not combine with other paracetamol products.
- Consult a healthcare professional if symptoms do not improve.
- Keep away from children and do not use to sedate them.
- Check with a doctor before use if you have a long-lasting cough, asthma, or cough with a lot of mucus.

Always follow the advice of healthcare professionals and read medication labels carefully. If you have any doubts or questions about medication use, it's best to consult with a doctor or pharmacist.

Taking other medicines

CNS depressants: Taking these with certain medications can make you very sleepy.

Antimuscarinic drugs: Can make some side effects stronger.

MAOIs and RIMAs: Don't use with certain allergy or cold medications because it can cause serious health issues.

Moclobemide: Can cause very high blood pressure if used with certain cold medications.

Blood pressure medicines: The cold medicine might stop them from working well.

Heart medicines: Can cause irregular heartbeats if taken with the cold medicine.

Ergot alkaloids: Can cause severe reactions if taken with the cold medicine.

Diet pills and stimulants: Can raise blood pressure if taken with the cold medicine.

Oxytocin: Can raise blood pressure if taken with the cold medicine.

Anticholinergic drugs: Effects can be stronger if taken with certain depression medications.

Paracetamol: Its absorption can be faster or slower depending on other drugs taken.

Blood thinners: Regular use of paracetamol can increase bleeding risk.

Liver enzyme inducers: Can make paracetamol less effective and clear it from the body faster.

Always check with a doctor or pharmacist before mixing medications to avoid harmful interactions.

Taking Corilief® 5 Flu tablets with food and drink

Take **Corilief® 5 Flu tablets** after food.

Pregnancy and breast-feeding

The ingredients in **Corilief® 5 Flu tablets** haven't been linked to harm in unborn babies, but it's still important to be careful when using any medication during the **early stages of pregnancy**.

Studies show that **paracetamol** is safe in the usual doses during pregnancy, but it's best to **listen to your doctor's advice**.

The ingredients do pass into breast milk, but there haven't been many problems reported. Still, it's recommended to use Corilief® 5 Flu tablets **with caution** while breastfeeding.

Paracetamol gets into breast milk too, but the amount is usually too small to cause issues. Breastfeeding is generally considered **safe** with paracetamol use according to current research.

Driving and using machines

Corilief® 5 Flu tablets may cause drowsiness. If patients are affected, they should not drive or use machinery.

c. How to take Corilief® 5 Flu tablets

Adults and children aged 16 years and over	Take two tablets, up to 4 times a day
Children 10 – 15 years	Take one tablet, up to 4 times a day

If you take more Corilief® 5 Flu tablets than you should

Paracetamol Overdose:

Taking more than 10 grams can cause liver damage in adults.

Even 5 grams can be harmful if you:

- Take certain epilepsy or tuberculosis medicines, or other drugs that affect the liver.
- Drink too much alcohol.
- Have health conditions like eating disorders or cystic fibrosis, or are malnourished.

Symptoms to Watch For:

Within the first day: paleness, nausea, vomiting, loss of appetite, and stomach pain.

After 12 to 48 hours: signs of liver damage.

Severe cases: problems with blood sugar, acid levels in the body, liver failure, bleeding, low blood sugar, brain swelling, coma, or death. Kidney damage and heart problems can also happen.

What to Do:

Go to the hospital right away if you think you've taken too much. Early signs might not show how serious it is. Activated charcoal can help if taken within an hour of the overdose. A medicine called N-acetylcysteine is most effective within 8 hours but can be used up to 24 hours later.

Diphenhydramine Overdose:

Can cause sleepiness, fever, and dry mouth. In severe cases, especially in kids: restlessness, shaking, seizures, and even coma or heart problems.

Pseudoephedrine Overdose:

Can cause nervousness, shaking, seizures, heart issues, high blood pressure, and trouble urinating.

General Treatment:

Supportive care is key. Emptying the stomach and using activated charcoal can help. For breathing or seizure issues, medical support is necessary. In some cases, speeding up the removal of the drug from the body may be needed.

If you forget to take Corilief® 5 Flu tablets

Do not take a double dose to make up for a forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed

d. Possible side effects

Like all medicines, Corilief® 5 Flu tablets can cause side effects, although not everybody gets them. Possible adverse effects include; **Blood and lymphatic system:** Rare blood disorders like low platelet or white cell counts.

Immune system: Allergic reactions, including rashes and increased sensitivity.

Mental health: Changes in mood or behavior, such as confusion, sadness, trouble sleeping, agitation, or hallucinations.

Nervous system: Feeling sleepy or less alert, headaches, unsteady movements, dizziness, shaking, or seizures.

Eyes: Blurry vision.

Heart: Fast heartbeat, irregular rhythm, or other heart-related issues.

Blood vessels: Low or high blood pressure.

Respiratory system: Thicker mucus in airways.

Digestive system: Upset stomach, dry mouth, nausea, or vomiting.

Liver: Problems with liver function.

Skin: Skin rashes.

Kidneys and urinary system: Difficulty in passing urine.

e. How to store Corilief® 5 Flu tablets

Keep out of the reach of children. Store below 30° C, in a dry environment away from light.

Do not use Corilief® 5 Flu tablets after the expiry date which is stated on the label. Do not use Corilief® 5 Flu tablets if you notice any visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

f. Further information

What Corilief® 5 Flu tablets contains

Corilief® 5 Flu tablet contains Diphenhydramine hydrochloride 12.5mg, Paracetamol 500mg and Pseudoephedrine hydrochloride 22.5mg

The other ingredients are- Pregelatinised Starch, Crospovidone,

Povidone K30, Croscarmellose sodium, Microcrystalline Cellulose, Stearic acid and Magnesium Stearate

What Corilief® 5 Flu tablet looks like and contents of the pack

Yellow oval-shaped tablets embossed with 4RFLU on one side and plain on the reverse side.

Category for Distribution:

Zimbabwe: P
Botswana: S3
Mozambique: Medicamento Sujeito a Receita Medica
Namibia: NS2
Tanzania: P
Rwanda: POM

Registration Number:

Zimbabwe: 2016/22.2.5/5281
Botswana: BOT2304034/ BOT2304034A
Mozambique: R5772
Namibia: 10/20.2.1/0313
Tanzania: TAN22HM0277
Rwanda: Rwanda FDA-HMP-MA-1066

NAME AND FULL PHYSICAL ADDRESS OF MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE:

Varichem Pharmaceuticals (Pvt) Ltd
194 Gleneagles Road
Willowvale
Harare
Zimbabwe
Tel: +263 (04) 620181-7

For any information about this medicinal product, please contact **Activis Pharma** supplier:

Company Name: **Activis Pharma**
Address: **P. O. Box 2927 Kigali**
KN 2 Ave, Rwezamenyo II - Nyarugenge
(Opposite St Andre college)
Country: **Rwanda**
Telephone: **+250 732 888 826**
E-Mail: activispharma@gmail.com

Date of Publication

07/2024