

	<b>BAL PHARMA LIMITED</b>	<b>Module - 1</b> Administrative Information and Product Information
	<b>LOFEN GEL (Diclofenac Sodium BP 1% w/w gel)</b>	
	<b>Dossier for Registration</b>	

## 1.4 Product information

### 1.4.3 Patient Information Leaflet(PIL)

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use LOFEN GEL safely and effectively. See full prescribing information for LOFEN GEL

DICLOFENAC SODIUM gel, 1%, for topical use only

#### WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning.

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.

Diclofenac sodium topical gel is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach and intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic disease and/or GI bleeding are at greater risk for serious GI events.

#### Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

- Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:
  - anytime during use

	<b>BAL PHARMA LIMITED</b>	<b>Module - 1</b> Administrative Information and Product Information
	<b>LOFEN GEL (Diclofenac Sodium BP 1% w/w gel)</b>	
	<b>Dossier for Registration</b>	

- without warning symptoms
- that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

NSAIDs should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as

different types of arthritis, menstrual cramps, and other types of short-term pain.

Who should not take NSAIDs? Do not take NSAIDs:

- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking NSAIDs, tell your health care provider about all of your medical conditions, including if you:

- have liver or kidney problems have high blood pressure
- have asthma
- are pregnant or plan to become pregnant. Talk to your health care provider if you are considering taking

NSAIDs during pregnancy. You should not take NSAIDs after 29 weeks of pregnancy.

- are breastfeeding or plan to breast feed.

Tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. Do not start taking new medicine without talking to your health care provider first.

What are the possible side effects of NSAIDs? NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”

	<b>BAL PHARMA LIMITED</b>	<b>Module - 1</b> Administrative Information and Product Information
	<b>LOFEN GEL (Diclofenac Sodium BP 1% w/w gel)</b>	
	<b>Dossier for Registration</b>	

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking your NSAID and call your health care provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands, and feet

If you take too much of your NSAID, call your health care provider or get medical help right away. These are not all the possible side effects of NSAIDs. For more information, ask your health care provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects.

Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your health care provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of NSAIDs

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

	<b>BAL PHARMA LIMITED</b>	<b>Module - 1</b> Administrative Information and Product Information
	<b>LOFEN GEL (Diclofenac Sodium BP 1% w/w gel)</b>	
	<b>Dossier for Registration</b>	

If you would like more information about NSAIDs, talk with your health care provider. You can ask your pharmacist or health care provider for information about NSAIDs that is written for health professionals.