SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PRODUCT

Felxicam 20 Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Piroxicam	20.00mg

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

Amethyst opaque/amethyst opaque capsule with “HD” printed on one end and “XCM20” printed on the other end of the capsule

4. CLINICAL PARTICULARS

Therapeutic indication

- For the symptomatic relief of pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.
- However, it should not be the first choice of non-steroidal anti-inflammatory drug (NSAID) treatment in these conditions.

4.2 Posology and Method of administration

Adult (Oral)

20 mg as a single daily dose.

Children (oral)

For juvenile chronic arthritis:

As little data are available in very young children, it is recommended that only children aged 6 years and older are treated with piroxicam according to the following dosage schedule:

Less than 15 kg bodyweight : 5 mg daily
16 to 25 kg bodyweight : 10 mg daily
26 to 45 kg bodyweight : 15 mg daily
More than 46 kg body weight : 20 mg daily

(Dosage recommendations and indications for use in children other than in juvenile chronic arthritis have not been established)

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Contraindication

- Piroxicam should not be prescribed to patients who are more likely to develop side effects, such as those with history of gastrointestinal disorders associated with bleeding or those who have had skin reactions to other medicines.
- Should not be used in patients sensitive to aspirin and non-steroidal anti-inflammatory drugs (NSAIDs).
- Should be avoided in patients with acute porphyria.
- Piroxicam should not be prescribed in association with any other NSAID or an anticoagulant.

Warnings and precautions

Precautions

- Should be used with caution in geriatric patients and in patients with upper gastrointestinal disease, cardiovascular disorders, hypertension, liver cirrhosis, nephrotic syndrome and impaired renal function.
- Safety for use in pregnancy has not been established.
- Not recommended for use in nursing mothers as clinical safety in neonates has not been established.
- Treatment should always be initiated by a physician experienced in the treatment of rheumatic arthritis.
- Use lowest dose (no more than 20 mg per day) and for the shortest duration possible. Treatment should be reviewed after 14 days.
- Always consider prescribing a gastroprotective agent

Warning

Risk of Gastrointestinal Ulceration, Bleeding and Perforation with NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAIDs therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

4.5 Drug Interactions

Concurrent use with the following drugs is not recommended:
Diuretic agents, aspirin, oral anticoagulants, cimetidine and lithium carbonate.

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Not applicable

Main Side/ Adverse Effects

- Side effects of piroxicam include gastrointestinal disturbances and bleeding, peptic ulceration, headache, dizziness, swollen eyes, blurred vision and eye irritations, malaise, tinnitus, skin rashes, pruritus, oedema, aplastic anaemia, paraesthesia, hair loss and severe hepatic reactions.
- Hypersensitivity reactions such as anaphylaxis, bronchospasm, urticaria/angioedema, vasculitis and serum sickness have been reported rarely.

4.9 Overdose

Clinical features:
Nausea, vomiting, abdominal pain, peptic ulceration, gastrointestinal bleeding, drowsiness, hyperreflexia, coma and convulsions.

Treatment:
Gastric lavage if appropriate. Symptomatic and supportive measures.
Cimetidine 200 mg IV 6 hourly and ranitidine 50 mg IV 6 hourly have been used prophylactically to treat peptic ulceration and gastrointestinal bleeding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Piroxicam is a non-steroidal anti-inflammatory analgesic. It has analgesic, anti-inflammmatory and anti-pyretic properties. It acts by inhibiting prostaglandin synthetase, an enzyme responsible for the synthesis of prostaglandin.

5.2 Pharmacokinetic properties

Piroxicam is well absorbed from the gastrointestinal tract. It is metabolized in the liver and excreted predominantly in the urine. It has a plasma half-life of approximately 50 hours and about 99% is bound to plasma proteins.

5.3 Preclinical Safety Data

Not applicable

6. PHARMACEUTICAL PARTICULARS

List of excipients

Lactose Monohydrate
Cornstarch
Polyvinylpyrrolidone K25
Polysorbate 80
Sodium Starch Glycolate
Magnesium Stearate
Colloidal Silicon Dioxide

Incompatibilities

Not applicable

Shelf life

3 years from date of manufacture

Special precaution for storage

Store below 30°C. Protect from light and moisture.

Nature and contents of container

Descriptions of each packaging material for Felxicam 20 Capusle is as below:

Immediate Container/Packaging

1	Material description	:	Rigid PVDC film
	Colour of film	:	Glass clear transparent
		:	
2	Material description	:	Felxicam 20 Capsule aluminium foil
	Specification	:	Foil property: Silver plain hard tempered 20 micron aluminium foil with 6276 primer on bright and heat seal on dull surface, 3-4 gsm.

Secondary Packaging Components

1	Material description	:	Felxicam 20 Capsule Insert
2	Material description	:	Felxicam 20 Capsule (10 x 10) Unit Box
3	Material description	:	PVC shrink-wrap Felxicam 20 Capsule (10 x 10) Unit Box
4	Material description		Plain carton for Felxicam 20 Capsule (10 x 10)

Instructions for use and handling <and disposal>

Not Applicable

7. MARKETING AUTHORISATION HOLDER

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer Name :
Name : HOVID Bhd.
Address : Lot 56442, 7 ½ Miles,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak., Malaysia.

8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

HOV/MAL/017

9. DATE OF FIRST AUTHORISATION

April 2016

10. DATE OF REVISION OF THE TEXT

August 2020