

ARTWORK FOR APPROVAL

Size: 150 mm x 120 mm

Board:

Grammage:

U/V: Print proof

Others: Code No.

Revised Artwork

1st Revised 16- 10 - 14

PRESCRIBING INFORMATION

Phlogin[®]

(Diclofenac Sodium)

فلوجين

COMPOSITION:

Phlogin 50 Capsules

Each capsule contains:
Diclofenac Sodium BP 50 mg
Mfg. Specs. Brookes

Phlogin SR-100 Capsules

Each capsule contains:
Diclofenac Sodium BP 100 mg

Phlogin Injection

Each 3 ml ampoule contains:
Diclofenac Sodium BP 75 mg
Mfg. Specs. Brookes

DESCRIPTION:

Phlogin (Diclofenac Sodium) is a non-steroidal, anti-inflammatory analgesic drug. Phlogin has potent anti-inflammatory, analgesic effect with anti-pyretic and uricosuric properties. Phlogin exerts its anti-inflammatory, analgesic and anti-pyretic effect by inhibiting the activity of prostaglandin synthetase, lysosomal enzyme and neutral proteolase.

PHARMACOKINETICS:

Phlogin 50 & Phlogin SR-100 Capsules

Phlogin (Diclofenac Sodium) is absorbed quickly from gastro-intestinal tract. Peak plasma concentration occurs in about 2 hours, plasma half-life is attained within 1-4 hours after ingestion. Phlogin (Diclofenac Sodium) does not accumulate in the body. After metabolism 2/3rd is excreted via kidney and 1/3rd via faeces.

Phlogin Injection

With a dose of 75 mg IM, the peak plasma concentration is attained within 10-22 minutes. Protein binding is 99.7%. Plasma half-life is 1-2 hours. The active substance is excreted via the kidneys in the form of metabolites. Less than 1% excreted as un-changed drug in the urine. The plasma concentration does not rise even in the presence of severe renal failure.

INDICATIONS:

Phlogin is indicated in all painful and inflammatory conditions i.e

- All inflammatory and degenerative forms of rheumatism e.g. Rheumatoid arthritis, Ankylosing spondylitis, Osteoarthritis
- Intervertebral disc syndrome i.e lumbago, sciatica
- Non-articular rheumatism e.g. bursitis, tendonitis, myositis etc
- Acute attacks of gout
- Renal colic
- Dysmenorrhoea
- Dental pain
- Post-operative and post-traumatic pain, inflammation and swelling

DOSAGE & ADMINISTRATION :

Phlogin 50 : One capsule 2-3 times a day.

Phlogin SR-100 : One capsule a day for maintenance therapy.

Phlogin Injection : For adults the dosage is generally one ampoule daily, injected deep intragluteally into the upper outer quadrant. In severe cases two injections separated by an interval of few hours can be given per day (One into each buttock), followed by capsules 50 & SR-100.

SIDE EFFECTS:

Phlogin is generally well tolerated. Patients may sometimes complain of mild headache, dizziness, nausea, diarrhoea, epigastric pain at the start of treatment which usually disappear within few days without discontinuation of therapy. Skin rashes, peripheral oedema and slightly increase in transaminase value have infrequently been reported.

CONTRAINDICATIONS:

Phlogin (Diclofenac Sodium) may not be used in patients with hypersensitivity to the active ingredient, peptic ulcer, porphyria and disturbances of haematopoiesis. Diclofenac Sodium is also contra-indicated in asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are known to be precipitated by acetylsalicylic acid or by any other agent with prostaglandin inhibiting activity.

CAUTIONS:

Diclofenac Sodium should be given with caution in patients with G.I.T. disorders, severe hepatic or renal damage. As with other drugs frequent blood count should be performed in patients on long term therapy. As with NSAID's the patients who have just had heart surgery should not take these medicines.

WARNING:

As with all NSAID's, these drugs can potentiate stomach bleeding in known case of peptic-ulcer disease.

USE IN PREGNANCY:

No teratogenic effect has so far been reported with Diclofenac Sodium at the recommended dosage. However Diclofenac Sodium could be given under compelling reasons particularly during the last 3 months of pregnancy.

DRUG INTERACTION:

Study in healthy subject indicates that Diclofenac Sodium decreases renal clearance of lithium. When given with preparations containing lithium, Diclofenac Sodium may raise their plasma concentration. Various NSAIDs are liable to inhibit the activity of diuretics thus monitoring the serum potassium level is essential. Concomitant use of glucocorticoids with NSAIDs may aggravate the G.I. side effects.

STORAGE:

Phlogin 50 & Phlogin SR-100 Capsules:
Store at temperature 15 to 30°C away from light & moisture.

PHLOGIN INJECTION:

Store at temperature 15 to 30°C away from light.

PRESENTATION:

PHLOGIN 50 Capsules : Pack of 20 Capsules
PHLOGIN SR-100 Capsules : Pack of 20 Capsules
PHLOGIN Injection : Pack of 5X3 ml Ampoule

خوراک اور طریقہ استعمال

فلوجن-50 کیپسول: ایک کیپسول دن میں دو سے تین مرتبہ

فلوجن ایس آر-100 کیپسول: ایک کیپسول دن میں ایک مرتبہ

فلوجن انجکشن:

بالغ:

ایک انجکشن دن میں ایک مرتبہ

طبیعت زیادہ خراب ہونے کی صورت میں کچھ گھنٹوں کے وقفے سے دو انجکشن بھی استعمال کئے جاسکتے ہیں

اسٹورینج:

فلوجن 50 اور فلوجن ایس آر-100 کیپسول:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی اور نمی سے بچا کر رکھیے

فلوجن انجکشن:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیے

Manufactured by:
Brookes Pharma (Private) Limited
58 & 59, Sector 15, Korangi Industrial Area,
Karachi, Pakistan.
Website: www.brookespharma.com
E-mail: marketing@brookespharma.com



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D.M. _____

Q.A. _____

Q.C. _____

M.A. _____

Prepared by: Shafiq Ahmed Siddiqui
Date: 29 - 01 - 2013