1.6 Product Information

1.6.1 Summary of Product Characteristics

1. Name of the Medicinal Product:

K-Flam Powder for Oral Solution 50 mg

2. Qualitative & Quantitative Composition:

Each sachet contains 50 mg Diclofenac Potassium.

3. Pharmaceutical Form:

Powder for Oral Solution.

4. Clinical Particulars:

4.1 Therapeutic indications

Short-term treatment in the following acute conditions:

- Post-traumatic pain, inflammation and swelling, e.g. due to sprains.
- Post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery.
- Painful and/or inflammatory conditions in gynaecology e.g. primary dysmenorrhoea or adnexitis.
- Migraine attacks.
- Painful syndromes of the vertebral column.
- Non-articular rheumatism.
- As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

4.2 Posology and method of administration

After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

The contents of the sachet should be dissolved with stirring in a glass of natural (non-carbonated) water. The solution may remain slightly opalescent, but this should not influence the efficacy of the preparation. The solution should be swallowed preferably before meals.

General target population:

The recommended initial daily dose is 100 to 150 mg. In milder cases, 50 to 100 mg daily is usually sufficient. The daily dose should generally be divided in up to 3 doses.

In primary dysmenorrhoea, the daily dose should be individually adjusted and is generally 50 to 150 mg. A dose of 50 to 100 mg should be given initially and, if necessary increased over the course of several menstrual cycles up to a total maximum of 200 mg/day. Treatment should be started on appearance of the first symptoms and depending on the symptomatology, continued for a few days.

In migraine, an initial dose of 50 mg should be taken at the first signs of an impending attack. In cases where pain relief within 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4 to 6 hours, not exceeding a total dose of 200 mg per day.

Special populations:

Paediatrics

K-Flam Powder for Oral Solution 50 mg is not recommended for use in children and adolescents below 14 years of age.

For adolescents aged 14 years and over, 50 to 100 mg daily are usually sufficient, given as 1 to 2 divided doses.

The maximum daily dose of 150 mg should not be exceeded.

The use of K-Flam Powder for Oral Solution 50 mg in migraine attacks has not been established in children and adolescents.

Geriatrics (Patients aged 65 or above)

No adjustment of the starting dose is required for elderly patients.

Renal impairment

No adjustment of the starting dose is required for renally impaired patients.

Hepatic impairment

No adjustment of the starting dose is required for hepatically impaired patients.

4.3 Contraindications

Known hypersensitivity to the active substance or to any of the excipients, active gastric or intestinal ulcer, bleeding or perforation, last trimester of pregnancy, severe hepatic, renal or cardiac failure. Like other non-steroidal anti-inflammatory drugs (NSAIDs), K-Flam Powder for Oral Solution 50 mg is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.

K-Flam Powder for Oral Solution 50 mg contains Aspartame which may be harmful for people with phenylketonuria.

4.4 Special warning & precautions for use

Warnings:

Cardiovascular thrombotic events

Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events including myocardial infarction and stroke, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk factors may also be at greater risk. To minimise the potential risk of an adverse cardiovascular event in patients taking an NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration.

There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.

Hypertension

NSAIDs may lead to the onset of new hypertension or worsening of pre-existing hypertension and patients taking anti-hypertensives with NSAIDs may have an impaired anti-hypertensive response.

Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.

Heart failure

Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

Gastrointestinal effects

Gastrointestinal bleeding, ulceration or perforation, which may increase with dose or duration of use and which can be fatal, have been reported with all NSAIDs, including Diclofenac, and may occur at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving K-Flam Powder for Oral Solution 50 mg, the medicinal product should be discontinued. Upper GI ulcers, gross bleeding or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk. Caution is advised in patients with risk factors for gastrointestinal events who may be at greater risk of developing serious gastrointestinal events, e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events. Doctors should warn patients about the signs and symptoms of serious gastrointestinal toxicity.

Severe skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TENS), have been reported very rarely in association with the use of NSAIDs, including K-Flam Powder for Oral Solution 50 mg. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity, and K-Flam Powder for Oral Solution 50 mg should be discontinued.

As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rare cases with Diclofenac without earlier exposure to the drug. Like other NSAIDs, K-Flam Powder for Oral Solution 50 mg may mask the signs and symptoms of infection due to its pharmacodynamic properties.

Precautions:

Geriatrics

Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight.

Interactions with other NSAIDs

The concomitant use of K-Flam Powder for Oral Solution 50 mg with systemic NSAIDs including cyclooxygenase-2 selective inhibitors, should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive adverse effects.

K-Flam Powder for Oral Solution 50 mg contains Aspartame, which may be harmful for people with phenylketonuria.

Pre-existing asthma

In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if

linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

Gastrointestinal effects

As with all NSAIDs, including Diclofenac, close medical surveillance is imperative and particular caution should be exercised when prescribing K-Flam Powder for Oral Solution 50 mg in patients with symptoms indicative of gastrointestinal (GI) disorders or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation. The risk of GI bleeding is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation and in the elderly.

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose.

Combination therapy with protective agents (e.g. proton pump inhibitors or misoprostol) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low-dose acetylsalicylic acid (ASA)/aspirin or other medicinal products likely to increase gastrointestinal risk.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding). Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, anti-platelet agents or selective serotonin-reuptake inhibitors.

Close medical surveillance and caution should also be exercised in patients with ulcerative colitis or Crohn's disease, as their condition may be exacerbated.

Hepatic effects

Close medical surveillance is required when prescribing K-Flam Powder for Oral Solution 50 mg to patients with impaired hepatic function, as their condition may be exacerbated.

As with other NSAIDs, including Diclofenac values of one or more liver enzymes may increase. During prolonged treatment with K-Flam Powder for Oral Solution 50 mg, regular monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash), K-Flam Powder for Oral Solution 50 mg should be discontinued. Hepatitis may occur with use of Diclofenac without prodromal symptoms.

Caution is called for when using K-Flam Powder for Oral Solution 50 mg in patients with hepatic porphyria, since it may trigger an attack.

Renal effects

As fluid retention and oedema have been reported in association with NSAID therapy, including Diclofenac, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion from any cause, e.g. before and after major surgery. Monitoring of renal function is recommended as a precautionary measure when using K-Flam Powder for Oral Solution 50 mg in such cases.

Discontinuation of therapy is normally followed by a recovery to the pre-treatment state.

Haematological effects

Use of K-Flam Powder for Oral Solution 50 mg is recommended only for short-term treatment. If, however, K-Flam Powder for Oral Solution 50 mg is used for a prolonged period, monitoring of the blood count is recommended, as with other NSAIDs. Like other NSAIDs, K-Flam Powder for Oral Solution 50 mg may temporarily inhibit platelet aggregation. Patients with defects of haemostasis should be carefully monitored.

4.5 Interaction with other medicinal products & other forms of interaction

The following interactions include those observed with K-Flam Powder for Oral Solution 50 mg and/or other pharmaceutical forms of Diclofenac.

Observed interactions to be considered

Potent CYP2C9 inhibitors: Caution is recommended when co-prescribing Diclofenac with potent CYP2C9 inhibitors (such as sulfinpyrazone and voriconazole), which could result in a significant increase in peak plasma concentrations and exposure to Diclofenac due to inhibition of Diclofenac metabolism.

Lithium: If used concomitantly, Diclofenac may raise plasma concentrations of lithium. Monitoring of the serum lithium level is recommended.

Digoxin: If used concomitantly, Diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive agents: Like other NSAIDs, concomitant use of Diclofenac with diuretics or antihypertensive agents (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors) may cause a decrease in their antihypertensive effect. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated, and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity.

Other NSAIDs and corticosteroids: Concomitant administration of Diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal adverse effects.

Anticoagulants and anti-platelet agents: Caution is recommended since concomitant administration could increase the risk of bleeding. Although clinical investigations do not appear to indicate that Diclofenac affects the action of anticoagulants, there are isolated reports of an increased risk of haemorrhage in patients receiving Diclofenac and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.

Selective serotonin reuptake inhibitors (SSRIs): Concomitant administration of systemic NSAIDs, including Diclofenac, and SSRIs may increase the risk of gastrointestinal bleeding.

Clinical studies have shown that Diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of the antidiabetic agents during treatment with Diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

Methotrexate: Caution is recommended when NSAIDs, including Diclofenac, are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.

Cyclosporin: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of cyclosporin due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving cyclosporin.

Drugs known to cause hyperkalemia: Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels, which should therefore be monitored frequently.

Quinolone antibacterials: There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

Phenytoin: When using phenytoin concomitantly with Diclofenac, monitoring of phenytoin plasma concentrations is recommended due to an expected increase in exposure to phenytoin.

4.6 Pregnancy & lactation

Pregnancy

There are insufficient data on the use of Diclofenac in pregnant women. Therefore, K-Flam Powder for Oral Solution 50 mg should not be used during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the foetus. As with other NSAIDs, use of Diclofenac during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.

Breast-feeding

Like other NSAIDs, Diclofenac passes into the breast milk in small amounts. Therefore, K-Flam

Powder for Oral Solution 50 mg should not be administered during breast feeding in order to avoid adverse effects in the infant.

Fertility

As with other NSAIDs, the use of K-Flam Powder for Oral Solution 50 mg may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of K-Flam Powder for Oral Solution 50 mg should be considered.

4.7 Effects on ability to drive & use machines

Caution is advisable when driving or operating machines as the medicine may make the patient dizzy, tired or sleepy. Eyesight problems have also been reported.

4.8 Undesirable Effects

The section below lists the adverse reactions identified through clinical trial experience and postmarketing surveillance by system organ class and frequency. Adverse reactions identified from post-marketing experience are included in italics. The frequency grouping is defined using the following convention:

very common	(≥ 1/10)
common	(≥ 1/100 to < 1/10)
uncommon	(≥ 1/1,000 to < 1/100)
rare	(≥ 1/10,000 to < 1/1,000)
very rare	(< 1/10,000)

Blood and Lymphatic System Disorders	
Very rare	Thrombocytopenia, leukopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis.
Immune System Disorders	
Rare	Hypersensitivity, anaphylactic and anaphylactoid

	reactions (including hypotension and shock).
Very rare	Angioedema (including face oedema).
Psychiatric disorders	
Very rare	Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.
Nervous system disorders	
Common	Headache, dizziness.
Rare	Somnolence.
Very rare	Paraesthesia, memory impairment, convulsion, anxiety, tremor, meningitis aseptic, dysgeusea, cerebrovascular accident.
Eye disorders	
Very rare	Visual impairment, vision blurred, diplopia.
Ear and labyrinth disorders	
Common	Vertigo.
Very rare	Tinnitus, hearing impaired.
Cardiac disorders	
Very rare	Palpitations, chest pain, cardiac failure, myocardial infarction.
Vascular disorders	
Very rare	Hypertension, vasculitis.
Respiratory, thoracic and mediastinal disorders	
Rare	Asthma (including dyspnea).
Very rare	Pneumonitis.
Gastrointestinal disorders	

Common	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, decreased appetite.
Rare	Gastritis, gastrointestinal haemorrhage, haematemesis, melaena, diarrhea haemorrhagic, gastrointestinal ulcer (with or without bleeding or perforation).
Very rare	Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, intestinal diaphragm disease, pancreatitis.
Hepatobiliary disorders	
Common	Transaminases increased.
Rare	Hepatitis, jaundice, liver disorder.
Very rare	Hepatitis fulminant, hepatic necrosis, hepatic failure.
Skin and subcutaneous tissue disorders	
Common	Rash
Rare	Urticaria
Very rare	Dermatitis bullous, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, alopecia, photosensitivity reaction, Henoch-Schonlein purpura, pruritus.
Renal and urinary disorders	
Very rare	Renal failure acute, haematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis.
General disorders and administration site conditions	
Rare	Oedema.

4.9 Overdose

Symptoms

There is no typical clinical picture resulting from Diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal haemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

Therapeutic measures

Management of acute poisoning with NSAIDs, including Diclofenac, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

Special measures such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs, including Diclofenac, due to the high protein-binding and extensive metabolism.

Activated charcoal may be considered after ingestion of a potentially toxic overdose, and gastric decontamination (e.g. vomiting, gastric lavage) after ingestion of a potentially life-threatening overdose.

5.0 Pharmacological Properties

Pharmacotherapeutic group, ATC: Anti-inflammatory and antirheumatic products, non-steroids acetic acid derivatives and related substances (ATC code: M01A B05).

K-Flam Powder for Oral Solution 50 mg contains the potassium salt of Diclofenac, a non-steroidal compound with pronounced analgesic, anti-inflammatory, and antipyretic properties. K-Flam Powder for Oral Solution 50 mg has a rapid onset of action, which makes it particularly suitable for the treatment of acute painful and inflammatory conditions. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered to be fundamental to its mechanism of action.

Prostaglandins play a major role in causing inflammation, pain, and fever. Diclofenac Potassium

in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in humans.

5.1 Pharmacodynamics

K-Flam Powder for Oral Solution 50 mg has been found to exert a pronounced analgesic effect in moderate and severe pain. In the presence of inflammation, e.g. due to trauma or following surgical interventions, it rapidly relieves both spontaneous pain and pain on movement and diminishes inflammatory swelling and wound oedema.

Clinical studies have also revealed that in primary dysmenorrhoea the active substance is capable of relieving the pain and reducing the extent of bleeding. In migraine attacks K-Flam Powder for Oral Solution 50 mg has been shown to be effective in relieving the headache and in improving the accompanying symptoms nausea and vomiting.

5.2 Pharmacokinetics

Absorption

Diclofenac is rapidly and completely absorbed from Diclofenac Potassium. Mean peak plasma concentrations of 5.5 micromol/L are attained after 5 to 20 minutes after ingestion of one sachet of 50 mg. Ingestion together with food is expected to have no influence on the amount of Diclofenac absorbed although onset and rate of absorption may be slightly delayed. Since about half of Diclofenac is metabolized during its first passage through the liver ("first pass" effect), the area under the concentration curve (AUC) is about half as large following oral or rectal administration as it is following a parenteral dose of equal size. Pharmacokinetic behaviour does not change after repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

Distribution

99.7 % of Diclofenac binds to serum proteins, mainly to albumin (99.4 %). The apparent volume of distribution calculated is 0.12 to 0.17 L/kg.

Diclofenac enters the synovial fluid, where maximum concentrations are measured 2 to 4 hours after peak plasma values have been reached. The apparent half-life for elimination from the synovial fluid is 3 to 6 hours.

Two hours after reaching peak plasma levels, concentrations of the active substance are already higher in the synovial fluid than in the plasma, and they remain higher for up to 12 hours. Diclofenac was detected in a low concentration (100 ng/mL) in breast milk in one nursing mother. The estimated amount ingested by an infant consuming breast milk is equivalent to a 0.03 mg/kg/day dose.

Biotransformation/metabolism

Biotransformation of Diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites (3'-hydroxy-, 4'-hydroxy-, 5-hydroxy-, 4',5 dihydroxy-, and 3'-hydroxy-4'-methoxy-Diclofenac), most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much lesser extent than Diclofenac.

Elimination

Total systemic clearance of Diclofenac from plasma is 263 ± 56 mL/min (mean value ± SD). The terminal half-life in plasma is 1 to 2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1 to 3 hours. One metabolite, 3'-hydroxy-4'-methoxy-Diclofenac, has a much longer plasma half-life. However, this metabolite is virtually inactive. About 60 % of the administered dose is excreted in the urine as the glucuronide conjugate of the intact molecule and as metabolites, most of which are also converted to glucuronide conjugates. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces.

Special population

No relevant age-dependent differences in the drug's absorption, metabolism or excretion have been observed. In patients suffering from renal impairment, no accumulation of the unchanged active substance can be inferred from the single-dose kinetics when applying the usual dosage schedule. At a creatinine clearance of less than 10 mL/min, the calculated steady-state plasma levels of the hydroxyl metabolites are about 4 times higher than in normal subjects. However, the metabolites are ultimately cleared through the bile.

In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of Diclofenac are the same as in patients without liver disease.

5.3 Preclinical Safety Data

Preclinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, mutagenicity, and carcinogenicity studies with Diclofenac revealed no specific hazard for humans at the intended therapeutic doses. In standard preclinical animal studies, there was no evidence that Diclofenac had a teratogenic potential in mice, rats or rabbits. Diclofenac had no influence on the fertility of parent animals in rats. Except for minimal fetal effects at maternally toxic doses, the prenatal, perinatal and postnatal development of the offspring was not affected. Administration of NSAIDs (including Diclofenac) inhibited ovulation in the rabbit and implantation and placentation in the rat and led to premature closure of the ductus arteriosus in the pregnant rat. Maternally toxic doses of Diclofenac were associated with dystocia, prolonged gestation, decreased fetal survival, and intrauterine growth retardation in rats. The slight effects of Diclofenac on reproduction parameters and delivery as well as constriction of the ductus arteriosus in utero are pharmacologic consequences of this class of prostaglandin synthesis inhibitors.

6. Pharmaceutical Particulars:

6.1. List of excipients:

S. No.	Material	Function
1.	Mannitol BP	Diluent
2.	Povidone BP (K-29/32)	Binder
3.	Potassium Bicarbonate BP	Alkalizing agent
4.	Acesulfame Potassium BP	Sweetening Agent
5.	Aspartame BP	Sweetening Agent
6.	Glycerol Dibehenate Ph. Eur.	Lubricant
7.	Aniseed Flavour	Flavoring agent
8.	Peppermint Flavour Permaseal (76175-51)	Flavoring agent
9.	Magna Sweet Plus	Taste masking agent

6.2. Incompatibilities*:*

None known

6.3. Shelf life:

36 months

6.4. Special precautions for storage*:*

Store below 30^0C.

Store in the original package in order to protect from moisture.

6.5. Nature & contents of container:

K-Flam Powder for Oral Solution 50 mg is packed in sachet using three layered laminate (12-micron PET, 12-micron Aluminum and 63 micron LDPE) placed in a printed carton along with a pack insert.

Pack size: 10 sachets & 30 sachets

6.6 Manufacturer:

Neopharma, Abu Dhabi, UAE

Plot No. A1 89-95,

Industrial City of Abu Dhabi (ICAD),

Mussafah, Abu Dhabi, UAE

6.7 Marketing Authorization Holder:

Neopharma, Abu Dhabi, UAE

Plot No. A1 89-95,

Industrial City of Abu Dhabi (ICAD),

Mussafah, Abu Dhabi, UAE