SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Flutab Sinus

2. Qualitative and quantitative composition
Each tablet contains 500mg Paracetamol and 30mg Pseudoephedrine HCl.
For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Tablet

4. Clinical particulars

4.1 Therapeutic indications
For the symptomatic relief of the symptoms of colds and influenza including feverishness, aches and pains, headache, nasal and sinus congestion (blocked nose and sinuses).

For Oral Administration

4.2 Posology and method of administration
Adults and children over 12 years

One tablet to be taken three or four times a day, up to a maximum daily dose of 4 tablets (120 mg pseudoephedrine and 2g paracetamol).

Elderly

Although no specific studies have been carried out in this age group, there is no need for dosage reduction in the elderly.

Children 6 to 12 years

Half a tablet to be taken four times a day, up to a maximum daily dose of 2 tablets (60 mg pseudoephedrine and 1g paracetamol).

This medicine is contraindicated in children under 6 years of age (see section 4.3).

Children of 6-12 years of age: not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Administration in those with hepatic disorders

Care should be taken in administering this product to patients with severe hepatic impairment.

Administration in those with renal disorders

Care should be taken in administering this product to patients with moderate to severe renal impairment.

Warning: Do not exceed the stated dose.
Keep all medicines out of the sight and reach of children.

4.3 Contraindications

FLUTAB SINUS is contraindicated in individuals with known hypersensitivity to the product or any of its components.

FLUTAB SINUS is contraindicated in patients with severe hypertension or coronary artery disease.

FLUTAB SINUS is contraindicated in patients who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks. The concomitant use of pseudoephedrine and this type of product may occasionally cause a rise in blood pressure.
Not to be used in children under the age of 12 years.

4.4 Special warnings and precautions for use

Caution in moderate to severe renal impairment.

Should be taken with caution by patients with hepatic impairment, prostatic enlargement and alcohol dependence.

If any of the following occur, the product should be stopped:

Hallucinations

Restlessness

Sleep disturbances

Not to be given to children under 6 years.

Do not take for longer than five days, unless your doctor agrees.

If symptoms persist, consult your doctor.

Do not take with any other decongestant-containing products.

Do not take with any other paracetamol-containing products.

Label

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet or combination label/leaflet

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of FLUTAB SINUS with tricyclic antidepressants, sympathomimetic agents (such as decongestants, appetite suppressants and amfetamine-like psychostimulants) or with monoamine oxidase inhibitors, which interferes with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure,[See Contraindications].

Because of the pseudoephedrine content, FLUTAB SINUS may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, betanidine, guanethedine, debrisoquine, methyldopa, alpha- and beta-adrenergic blocking agents, [See Special warnings and precautions for use].

Patients who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged. Alcohol can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induce liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Fertility, pregnancy and lactation

The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, the use of the product during pregnancy should be avoided. The amounts of paracetamol and pseudoephedrine secreted into breast milk are considered to be too small to be harmful.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Pseudoephedrine

Serious side effects associated with the use of pseudoephedrine are rare. Symptoms of central nervous system excitation may occur, including sleep disturbance and, rarely, hallucinations.

Skin rashes, with or without irritation, have occasionally been reported with pseudoephedrine.

Urinary retention has been reported occasionally in men receiving pseudoephedrine: prostatic enlargement could have been an important predisposing factor.

Paracetamol

Paracetamol has been widely used and, when taken at the usual recommended dosage, side effects are mild and infrequent and reports of adverse reactions are rare. Skin rash and other allergic reactions occur rarely.

Most reports of adverse reactions to paracetamol relate to overdose with the drug.

There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic dosages of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of their disease improved after paracetamol withdrawal.

Nephrotoxic effects following therapeutic dosages of paracetamol are uncommon. Papillary necrosis has been reported after prolonged administration.

To report any side effect(s):

- ☐ The National Pharmacovigilance and Drug Safety Centre (NPC)
  - o Fax: +966-11-205-7662
  - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
  - o Toll free phone: 8002490000
  - o E-mail: npc.drug@sfda.gov.sa
  - o Website: www.sfda.gov.sa/npc

4.9 Overdose

Immediate symptoms of overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia, abdominal pain, irritability, restlessness, palpitations, hypertension, difficulty in micturition, thirst and convulsions.

Liver damage may become apparent 12 to 48 hours after ingestion. Though hepatic enzymes may become elevated and prothrombin time prolonged within 10-12 hours of paracetamol overdosage, clinical symptoms may not be apparent for 1 to 6 days following ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatits have been reported.

In paracetamol overdosage with hepatic damage, paracetamol half life is often prolonged from around 2 hours in normal adults to 4 hours or longer. Liver damage and nephrotoxic effects have been reported after the daily ingestion of excessive amounts of paracetamol.

Liver damage is likely in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of overdosage. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage and activated charcoal administered to reduce paracetamol absorption. As peak plasma concentrations may be delayed by up to 4 hours following overdose, to accurately assess the risk of hepatotoxicity, plasma paracetamol levels should be measured at least 4 hours post-ingestion.

Generally treatment is required if the blood-paracetamol concentration is higher than a line drawn on semi-log/linear paper joining the points 200mg per litre (1.32 mmol/litre) at 4 hours and 30mg per litre (0.2mmol/litre) at 15 hours following ingestion. Administration of oral methionine or intravenous N-acetylcysteine, which may have a beneficial effect up to at least 48 hours after overdose, may be required. It has been proposed that the threshold for treatment with N-acetylcysteine should be reduced by 30-50% in patients taking drugs which induce hepatic enzymes, who abuse alcohol long-term or who are chronically malnourished. These patients may be more susceptible to toxic effects of paracetamol.

Symptomatic and supportive measures should be undertaken, particularly with regard to the cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Paracetamol is a peripherally acting analgesic with antipyretic activity.

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

The rate and extent of paracetamol absorption is normal in the elderly but plasma half life is longer and paracetamol clearance lower than in young adults.

In renal impairment though the mean plasma half-life of paracetamol is similar in normal and renally impaired subjects at 2-8 hours, from 8-24 hours paracetamol is eliminated less rapidly. An increase in the interval between doses of paracetamol has been recommended for adults with chronic renal failure.

With severe hepatic impairment the mean plasma half life of paracetamol is significantly prolonged (by approximately 75%). The clinical significance of this is however unclear, as no evidence exists of drug accumulation or hepatotoxicity in patients with liver disease.

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted in the urine unchanged. It has an elimination half-life of 5 to 8 hours but its urinary elimination and hence half-life is pH dependent. Pseudoephedrine is rapidly distributed throughout the body, its volume of distribution being 2 to 3L/Kg bodyweight.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch, Sodium Starch Glycolate, Maize Starch Pregelatinized, Povidone 30, Stearic Acid (P.B.C), Sicovit Tartrazine 85E 102, Sicovit Tartrazine 85E 131, Anhydrous Sodium Sulphate, and Purified Water

6.2 Incompatibilities

None

6.3 Shelf life

36 Months/ 3 years

6.4 Special precautions for storage

Do not store above 30°C.

Store in the original package.

6.5 Nature and contents of container

Each pack contains 20 tablets in White Opaque PVC/PVDC Blister Strip and Aluminium Foil

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder

SPIMACO
Al Qassim pharmaceutical plant
Saudi Pharmaceutical Industries &
Medical Appliance Corporation

8. Marketing authorisation number(s)

04665/6344/NMR/2018

9. Date of first authorisation/renewal of the authorisation

Oct 9, 2019

10. Date of revision of the text

June 2014