National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

SUREX NIGHT Paracetamol 500mg+Diphenhydramine HCl 25mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol 500mg

Diphenhydramine HCl 25mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

It is tablet.
Administered for oral.

4. Clinical particulars

4.1 Therapeutic indications

Surex Night is indicated for the treatment of pain such as headache, migraine, backache, rheumatic and muscle pain, neuralgia, toothache or period pain.

4.2 Posology and method of administration

Adults and children aged 12 years and over: swallow 2 tablets with water, 20 minutes before you go to bed.

- Do not take Surex night if you have already taken 4 doses of a paracetamol containing product during the day.
- Do not take more than 2 tablets in 24 hours.
- Do not take more than the recommended dose.
- Do not take if you are under 12 years.

4.3 Contraindications

Surex Night is contraindicated in pregnant women and breast feeding mothers.

4.4 Special warnings and precautions for use

Do not take Surex Night:

If you have ever had an allergic reaction to paracetamol, diphenhydramine hydrochloride.

- If you have porphyria (too much of the pigment called porphyrin which may discolour the urine).
- If you have taken another medicine containing paracetamol in the last 4 hours.

Do not take with any other antihistamine- containing products.

Ask your doctor before you take this medicine:

- If you have liver or kidney disease, including alcoholic liver disease.

- If you have epilepsy, or seizure disorders.
- If you have an obstruction in your stomach or gut (for example because of an ulcer).
- If you experience difficulty passing urine.
- If you have narrow glaucoma (raised pressure in the eye).
- If you have enlarged prostrate.
- If you have myasthenia gravis.
- If you have asthma, bronchitis or chronic obstructive pulmonary disease (COPD).
- If you have been told by your doctor that you have intolerance to some sugars.

WARNING:

- Do not drive or operate machinery. Surex Nigth is intended to produce drowsiness or sleepiness soon after dose is taken.

Do not drink alcohol while using Surex Night.

4.5 Interaction with other medicinal products and other forms of interaction

Surex Night interacts with monoamine oxidase inhibitors (MAOIs) if taken in the last 2 weeks or tricyclic antidepressants (prescribed for depression); atropine; metoclopramide or domperidone (for nausea or vomiting); colestyramine (to lower blood cholesterol); medicines for stomach cramps (example dicycloverine) or travel sickness (e.g. hyoscine); medicines to treat anxiety or to help you sleep; medicines that make you drowsy or give you a dry mouth; or blood thining drugs (anticoagulants e.g. warfarin).

4.6 Pregnancy and Lactation

4.6.1 Pregnancy:

The U.S. Food and Drug Administration (FDA) is aware of and understands the concerns arising from recent reports questioning the safety of prescription and overthe-counter (OTC) pain medicines when used during pregnancy. As a result, we evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. We urge pregnant women to always discuss all medicines with their health care professionals before using them.

4.6.2 Lactation:

There are no data on the presence of artemether or lumefantrine in human milk, the effects on the breastfed infant or the effects on milk production. Artemether and lumefantrine are transferred into rat milk. When a drug is transferred into animal milk, it is likely that the drug will also be transferred into human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Coartem and any potential adverse effects on the breastfed infant from Coartem or from the underlying maternal condition.

4.6.3 Fertility:

Contraception

Use of Coartem may reduce the efficacy of hormonal contraceptives. Advise patients using hormonal contraceptives to use an alternative non-hormonal contraceptive method or add a barrier method of contraception during treatment with Coartem.

Infertility

In animal fertility studies, administration of repeated doses of artemether-lumefantrine combination to female rats (for 2 to 4 weeks) resulted in pregnancy rates that were reduced by one half. In male rats dosed for approximately 3 months with artemether-lumefantrine

combination, abnormal sperm cells, decreased sperm motility, and increased testes weight were observed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.
Undesirable effects

Like all medicines, Surex Night can have side effects, but not everybody gets them. Older people are more prone to the side effects. These side effects may include the following;

- Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating
- Dry mouth
- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- Chest tightness or thickening of phlegm.
- Difficulty in passing urine, headaches.
- Skin rash or peeling or mouth ulcers.
- Stomach upset.
- Breathing problems. These are more likely if you have experienced them before when taking other pain killers (such as ibuprofen and aspirin).
- Seizures or difficulty of muscle coordination.
- Changes in heart rhythm.
- Unexplained bruising or bleeding.

These reactions are rare.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

4.8 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Propacetamol is hydrolyzed to paracetamol and then it presents a weak inhibition of COX-1 and COX-2 which is translated into a low anti-inflammatory activity. Therefore, in high inflammatory conditions, such as rheumatoid arthritis, these agents show limited in vivo suppression of inflammation and platelet activity. The formation of N-arachidonoylphenolamine, donates paracetamol with analgesic and antipyretic properties.

5.2 Pharmacokinetic properties

Paracetamol

Pharmacokinetics

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours.

Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine), is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate following paracetamol overdosage and cause tissue damage.

Absorption.

The absorption of paracetamol was slow and incomplete in vegetarian subjects compared with non-vegetarian subjects

Diphenhydramine hydrochloride

Pharmacokinetics

Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract, although high first-pass metabolism appears to affect systemic availability. Peak plasma concentrations are achieved about 1 to 4 hours after oral doses. Diphenhydramine is widely distributed throughout the body including the CNS. It crosses the placenta and has been detected in breast milk. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Sodium Starch Glycolate, Silicon dioxide, Magnesium Stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a cool and dry place below 30℃

Keep out of reach of children

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Primary package:
Aluminium foil for drug use

Size and specification

Thickness(mm)		Width(mm)		Length(mm)	
Base size	deviation	Base size	deviation	Base size	deviation
0.024	±0.003	50-800	±0.5	1000	±20

Seal inner packing in bag of low density polyethylene solid for drug use. Keep in clean, ventilated place.

Second package:
Light resistance PVC Sheet for Solid Pharmaceutical Packaging

Size and specification

Items	Size (mm)	Allowed deviation (mm)
Width (mm)	≥300	±2
	< 300	±1
Thickness (mm)	0.20-0.40	±0.02

10 tablets per PVC/Alu blister
1blister/box or 10 blisters/box

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. APPLICANT/MANUFACTURER

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