MODULE 1.3 – PRODUCT INFORMATION

Applicant – SM PHARMACEUTICALS SDN. BHD.
Name – Xetec Tablet 10 mg
Module 1 – Administrative information and prescribing information

1.3 Product Information:

1.3.1 Summary of product characteristics (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Xetec Tablet 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetirizine Hydrochloride (Active Ingredient)	10.000 mg
Microcrystalline Cellulose	20.000 mg
Corn Starch (Dry Mixing)	25.000 mg
Sodium Starch Glycolate (Dry Mixing)	4.500 mg
PVP-K30	3.000 mg
Corn Starch (for Blending)	5.000 mg
Sodium Starch Glycolate (Blending)	3.000 mg
Magnesium Stearate	2.000 mg
Lactose Monohydrate	45.000 mg
Purified Water	0.060 ml
Hydroxy Propyl Methyl Cellulose E5	3.500 mg
Ethyl Cellulose	0.450 mg
Titanium Dioxide	0.550 mg
Purified Talcum	0.200 mg
Polyethylene Glycol 400	0.400 mg
Polyethylene Glycol 4000	0.400 mg
PEG 6000	1.767 mg

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. It is also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.

4.2 Posology and method of administration

In children 3 to 6 years old: 5 mg once daily or 2.5 mg twice daily.
In children 6 years old or above: 10 mg once daily or 5 mg twice daily.

In adults: 10 mg once daily. In patients with renal insufficiently, dosage should be reduced to half the daily dose. It is advisable to take the drug with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night. In patients affected by side effects, the dose may be taken as 5 mg in the morning and 5 mg in the evening.

4.3 Contraindications

Patients with a history of hypersensitivity to any of Xetec constituents, pregnant women during first three months of pregnancy and Xetec is contraindicated during lactation.

4.4 Special warning and precautions for use

Activities requiring mental alertness: In clinical trials the occurrence of somnolence has been reported in some patients taking Cetirizine. Due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.
At therapeutic doses, Xetec does not potentiate the effects of alcohol (at blood level of 0.8 g/l). Care should, however, be taken.
The safety and effectiveness of cetrizine in pediatric patients under the age of 2 years have not been established.

4.5 Interaction with other medicinal products and other forms of Interactions

To date, there are no known interactions with other drugs. Nevertheless, Xetec should be used with caution if sedatives are also being taken.

4.6 Pregnancy and Lactation

Teratology studies in animals have not demonstrated any special malformations. As a precaution, Xetec should not be administered to pregnant women during the first three months of pregnancy. Xetec is contraindicated in lactating women since the active ingredient, cetirizine is excreted in breast milk.

4.7 Effects on ability to drive and use machine

Be careful when driving or operating machine until you know how Xetec will affects you

4.8 Undesirable effects

There have been occasional reports of mild and transient subjective side-effects such as headache, dizziness, drowsiness, agitation, dry mouth and gastro-intestinal discomfort.
In objective tests of psychomotor function, the incidence of sedaction with cetrizine was similar to that of placebo. Occasionally symptoms of hypersensitivity have been reported.

4.9 Overdose and special antidotes.

Drowsiness can be symptoms of overdosage, occurring from administration of 50mg of Xetec as a single dose.

To date, there is no specific antidote. In the case of massive overdosage, gastric lavage should be performed as soon as possible. Usual supportive measures should be provided and routine observations carried out regularly.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In experimental animals, Cetirizine has been shown to be an anti- H_1 agent devoid of any significant anticholinergic or antiserotonin effects. At pharmacologically active doses, it induces neither sedation nor behavioural changes. This may be explained by the fact that Cetirizine does not cross the blood-brain barrier. It was shown in human pharmacology studies that Cetirizine will inhibit certain effects produced by exogenous histamine. This activity appears rapidly. Cetirizine also inhibits the effects produced by endogenous histamine released *in vivo* by an agent, eg 48/80. Finally, it inhibits the cutaneous reaction induced by VIP (Vasoactive Intestinal Polypeptide) and substance P, neuropeptides which are believed to take part in the allergic reaction.

Cetirizine inhibits the histamine-induced "early" phase of the allergic reaction. It also significantly reduces the migration of inflammatory cells such as eosinophils and the release of mediators associated with the "late" allergic response.

Cetirizine markedly reduces bronchial hyper-reactivity to histamine in the asthmatic patient. It also reduces the allergic reaction induced by specific allergens. These effects are obtained without any central effects being demonstrated either by psychometric test or by a quantified EEG.

5.2 Pharmacokinetic properties

Peak blood level of the order of 0.3 micrograms / ml are reached between 30 and 60 minutes after administration of a 10 mg dose of Xetec. Its plasma half-life is approximately 10 hours in adults, 6 hours in children aged 6 to 12 years and 5 hours in children aged 2 to 6 years. These data are consistent with the urinary excretion half-life of the drug. The cumulative urinary excretion represents about two third of the dose given in both adults and children. Consequently, the apparent plasma clearance in children is higher than in adults. Absorption is very consistent from one subject to the next. The plasma levels are proportional to the administered dose. Cetirizine is strongly bound to plasma protein.

5.3 Preclinical safety data

Carcinogenicity / Tumorigenicity / Mutagenicity
Long-term animal studies to evaluate carcinogenic, tumorigenic, or mutagenic potential of most antihistamines have not been performed.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients

Microcrystalline Cellulose
Corn Starch (Dry Mixing)
Sodium Starch Glycolate (Dry Mixing)
PVP-K30
Corn Starch (for Blending)
Sodium Starch Glycolate (Blending)
Magnesium Stearate
Lactose Monohydrate
Purified Water
Hydroxy Propyl Methyl Cellulose E5
Ethyl Cellulose
Titanium Dioxide
Purified Talcum
Polyethylene Glycol 400
Polyethylene Glycol 4000
PEG 6000

6.2 Incompatibilities:

Not Applicable

6.3 Shelf Life:

3 years

6.4 Special Precautions for Storage

Store in a dry place, below 30°C. Protect from light and freezing.

6.5 Nature and Contents of Container

Printed Box of 100 x 10's

6.6 Instruction for Use and Handling

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

Applicant – SM PHARMACEUTICALS SDN. BHD.
Name – Xetec Tablet 10 mg
Module 1 – Administrative information and prescribing information

7.1 NAME AND ADDRESS OF MANUFACTURER

SM PHARMACEUTICALS SDN BHD
L0T 88, SUNGAI PETANI INDUSTRIAL ESTATE
08000 SUNGAI PETANI
KEDAH DARUL AMAN
MALAYSIA

7.2 NAME AND ADDRESS OF PRINCIPAL

COSMAS MUKARATIRWA
ERF 492, DANTE STREET, PROSPERITA
WINDHOEK, NAMIBIA

8. REGISTRATION NUMBER:

9. CATEGORY FOR DISTRIBUTION

"P.P" – Prescription Preparations – this category are available from pharmacies/discrepancies only.

10. DATE OF PUBLICATION OF THIS PACKAGE INSERT

13.09.2018