SUMMARY OF PRODUCT CHARACTERISTICS

1- Product name:

Metsil® Fort 80 mg Chewable Tablet

2- Qualitative and Quantitative Composition:

Each Fort Chewable Tablet contains;

Simethicone 80 mg, (Sodium saccharin as sweetener; Menthol as aromatic agent)

3- Pharmaceutical Form:

Fort Chewable Tablet

4- Clinical Information:

4-1-Therapeutic Indication:

Metsil® Fort Chewable Tablet 80 mg is used for relief of the symptoms of excess gas in the digestive tract. Metsil® Fort Chewable Tablet is high capacity antiflatulent for adjunctive treatment of many conditions in which the retention of gas may be a problem, such as the following: aerophagy, functional dyspepsia, postoperative gaseous distention, peptic ulcer, spastic or irritable colon, diverticulosis, postcholecystecthomy syndrome, chronic cholecystitis, radiological examination of the intra abdominal structures (such as gall bladder, bowel, kidney)

4-2-Administration and dosage:

Metsil® Fort Chewable Tablet 80 mg is recommended one tablet four times daily after meals and at bedtime.

For relief of unwanted gas, two tablet three times daily, starting three days before the radiological examination, must be taken.

Do not take more than 500 mg per day except under the advice and supervision of a physician, although it is used along with as combination with different antasids up to 2g.

4-3-Contraindication:

As Metsil® Fort Chewable Tablet 80 mg is physiologically inert, no contraindication of its use is known.

4-4-Warnings and Precaution:

Simethicone is not toxic and no side effect of its use is reported.

4-5-Drug and other Interactions:

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4-6-Usage in Pregnancy and Lactation:

Pregnancy risk category is B. Because there is a deficiency in the controlled studies on people, it should be used by considering the benefit and harm ratio.
It is not recommended for the children in infantile colic medication .because there is not enough information about its reliability.

4.7- Operating machinery or driving a motor vehicle:

There is no information about the effects on ability to drive and use machines for Simethicone

4-8-Side Effects:

Side effects have not been reported with the use of Metsil® Fort Chewable Tablet 80 mg.
IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

4-9-Overdosage:

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5- Pharmacological Properties:

Pharmacodynamic Properties:

Active ingredient of Metsil® Fort Chewable Tablet 80 mg is simethicone called also "activated dimethicone". Metsil® Fort Chewable Tablet has a defoaming action that relieves flatulence by dispersing and preventing the formation of mucus-surrounded gas pockets in the gastrointestinal tract.

Pharmacokinetic properties:

Metsil® Fort Chewable Tablet act in the stomach and intestines to change the surface tension of gas bubbles enabling them to coalesce, thereby liberating and eliminating the gas easier by belching or passing flatus. METSİL® is physiologically inert and there is not any report of toxication. After the oral administration, simethicone is excreted unchanged in the feces.

5-3-Preclinical safety data :

Not appliacable

6- Pharmaceutical Particulars :

6.1.- List of excipients :

Sodium saccharin dihydrate
Lactose Monohydrate
Mannitol 60
Magnesium stearate .
Povidone K-30
Colloidal anhydrous silica (Aerosil 200)
Microcrystalline cellulose (Avicel pH 102)
Menthol crystal

6.2- Incompatibilities : There are no incompatibilities between excipient-excipient or excipient – active ingredient or finished product – packaging material.

6.3– Shelf Life :

36 months

6.4- Special precautions for storage :

Store below 30 ^{o}C, at room temperature

Keep out of reach of children and in its original package .

6.5- Nature and contents of container :

Al/PVC blister package 50 tablets.

6.6- Instructions for use / handling :

None.

6.7- Special precautions for disposal of unused medicinal products

None.

7.- Classification

Sold with prescription only

8.- Marketing Authorization Holder :

Registration Holder : BİLİM PHARMACEUTICALS
ISTANBUL/TURKEY

9.- Marketing Authorization Number :

05338/07441/REN/2020

10.- Date of First Authorization / Renewal of Authorization:

Sep 23, 2020

11.- Data of Last/Partial Revision of the Text :

21.09.2011