ZYMAFLUOR®

SCHEDULING STATUS S1

PROPRIETARY NAME AND DOSAGE FORM
Zymafluor® Tablets
Zymafluor® Drops

COMPOSITION
Zymafluor® Tablets contain: 0,55 mg Sodium fluoride equivalent to 0,25 mg fluoride per tablet.
Inactive ingredients: colloidal anhydrous silica, magnesium stearate and peppermint oil.

Zymafluor® Drops contain: 1 ml oral drop solution contains 2,52 mg sodium fluoride, equivalent to 1,14 mg fluoride.

Inactive ingredients: glycerol and purified water, benzoic acid 0,15 % *m/v* as preservative.

Zymafluor® contains: Sorbitol

PHARMACOLOGICAL CLASSIFICATION
A 24 Mineral substitutes, electrolytes.

PHARMACOLOGICAL ACTION
The protective action of **Zymafluor®** is due to its accumulation in the outer layers of the dental enamel. Before the teeth erupt, **Zymafluor®** is carried to the developing teeth by the bloodstream and thus permits effective fluoridation before the teeth appear. After their eruption the teeth take up fluoride by way of direct contact with the fluoride contained in the saliva. **Zymafluor®** tablets should thus not be swallowed whole but should be allowed to dissolve slowly in the mouth.

INDICATIONS
Prophylaxis of dental caries.
The administration of **Zymafluor®** is recommended solely for the prevention of tooth decay and should be considered when water supplies are fluoride deficient.
Special note: there is no convincing evidence that fluoride from any source reduces the development of caries after the permanent teeth are formed (usually about age 14).

CONTRAINDICATIONS
Zymafluor® is contraindicated in kidney disease.
Hypersensitivity to sodium fluoride.
Zymafluor® should not be used until the fluoride concentration in the drinking water supply is known.
Use must be especially avoided in regions in which fluoridation is practised in the form of addition of fluoride to table salt or the drinking water supply.

WARNINGS
If the water contains more than 0,7 mg/l of fluoride, supplementation is not recommended. To avoid overdosage, allowance should be made for fluorides ingested from other sources such as the diet or fluoride toothpastes.
Contains sorbitol and may have a laxative effect.
Patients with the rare hereditary condition of sorbitol/maltitol/lactitol intolerance should not take **Zymafluor®**.

DOSAGE AND DIRECTIONS FOR USE
If not otherwise prescribed by a doctor or dentist the following dosages are recommended as a guideline:

Age	*0 to 2 years*	*2 to 4 years*	*4 to 14 years and over*
Drinking water containing less than 0,3 mg/l of fluoride	1 tablet or 4 drops daily	2 tablets or 8 drops daily	4 tablets or 16 drops daily
Drinking water containing less than 0,3 to 0,7 mg/l of fluoride	Nil	1 tablet or 4 drops daily	2 tablets or 8 drops daily
Drinking water containing more than 0,7 mg/l of fluoride	Nil	Nil	Nil

Administration should begin in very early childhood.
Four drops or one tablet of 0,25 mg (which should be crushed and dissolved in a little water) should be added to a bottle (not of milk) or solid meal, or administered alone. As soon as the age of the child permits, **Zymafluor®** tablets should no longer be swallowed, but sucked slowly in the mouth, between the cheek and gum, sometimes on the left and sometimes on the right side. They are best taken in the evening before bedtime, after brushing the teeth as in this way high fluoride concentration in the mouth can be maintained for a longer period.
Please consult your local Dentist, Pharmacist, Medical Doctor or Medical Officer of Health to ascertain whether **Zymafluor®** supplementation is necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
The major manifestations or signs of the chronic ingestion of excessive amounts of fluoride are mottled enamel of the teeth and osteosclerosis (a phenomenon wherein the density and calcification of bone are increased). Clinical signs are joint pain, stiffness, limited movement and in severe cases crippling deformity.
Do not exceed the recommended dose. Keep out of the reach of young children.

INTERACTIONS
Absorption of fluoride is inhibited by calcium, magnesium or aluminium. **Zymafluor®** should therefore not be given with milk and dairy products, nor with antacids containing calcium, aluminium or magnesium salts.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
In acute poisoning, sodium fluoride taken by mouth is corrosive, forming hydrofluoric acid in the stomach.
Initial symptoms are secondary to the local action of fluoride on the mucosa of the gastrointestinal tract. Ingestion of more than 250 mg of sodium fluoride may frequently cause salivation, nausea, abdominal pain, vomiting and diarrhoea. (NB. i.e. nearly 450 **Zymafluor®** tablets or 1800 drops).
Systemic symptoms are varied and severe. Large doses cause thirst, perspiration, paralysis, muscular weakness and clonic convulsions, followed by respiratory and cardiac failure; there may be renal failure; death may occur within 2 to 4 hours.
The patient shows signs of increasing irritability of the nervous system, including paraesthesias, a positive Chvostek sign, hyperactive reflexes and tonic and clonic convulsions. Metabolic and electrolyte disturbances may occur.
Hypocalcaemia and hypoglycaemia are frequent laboratory findings. The signs may be delayed for several hours. Pain in various muscle groups may occur. The blood pressure falls, presumably due to central vasomotor depression as well as a direct toxic action on cardiac muscle. The respiratory centre is first stimulated and later depressed.
It is stated that the lethal dose of sodium fluoride for adults is about 5 to 10 g, whereas dangerous poisoning has been reported after oral doses of less that 1 g. In children 0,5 g of sodium fluoride may be fatal (NB i.e. nearly 900 **Zymafluor®** tablets or 3600 drops).
Ocular damage has also been reported.

TREATMENT
Contact your nearest hospital without delay. Treatment is symptomatic and supportive.

The principles of the treatment are as follows:
1. Act quickly.
2. In acute poisoning, empty the stomach by aspiration and lavage with lime water or a 1 % solution of calcium chloride or other calcium salt.
3. Calcium gluconate injection, 10 ml of a 10 % solution, may be given intravenously to control convulsions and repeated every 4 to 6 hours if needed.
4. Morphine or pethidine may be given by injection if necessary, to control colic.
5. The circulation should be maintained with infusions of suitable electrolyte solutions.
6. The respiration may require assistance.
7. Haemodialysis has been used.
8. Wash away vomitus, faeces and urine promptly to prevent external burns.

IDENTIFICATION
Tablets: White, round, biconvex tablets: diameter approximately 4 mm, thickness approximately 2,6 mm.
Drops: Clear, colourless and odourless solution.

PRESENTATION
Tablets: Plastic containers of 150 and 400 tablets.
Drops: Plastic containers of 20 ml.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Keep container tightly closed.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS
Tablets: E/24/728
Drops: Y/24/394

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republic of South Africa

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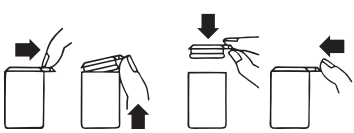

Zymafluor® Tablets
Namibia: Reg. No.: 90/24/00683; Schedule 1

Zymafluor® Drops
Namibia: Reg. No.: 10/24/0513; Schedule 1

Mylan

www.mylansa.co.za

ZYMAFLUOR®

SKEDULERINGSTATUS S1

EIENDOMSNAAM EN DOSEERVORM
Zymafluor® Tablette
Zymafluor® Druppels

SAMESTELLING
Zymafluor® Tablette bevat: 0,55 mg Natriumfluoried ekwivalent aan 0,25 mg fluoried per tablet.

Onaktiewe bestanddele: kolloïdale anhidriese silika, magnesiumstearaat en pepermentolie.

Zymafluor® Druppels bevat: 1 ml orale druppel oplossing bevat 2,52 mg natruimfluoried, ekwivalent aan 1,14 mg fluoried.

Onaktiewe bestanddele: gliserol en gesuiwerde water, bensoësuur 0,15 % *m/v* as preserveermiddel.

Zymafluor® bevat: Sorbitol

FARMAKOLOGIESE KLASSIFIKASIE
A 24 Aanvullende mineraalpreparate, elektroliete.

FARMAKOLOGIESE WERKING
Die beskermende werking van **Zymafluor®** is te danke aan die ophoop daarvan in die buitenste lae van die tandemalje. Voor erupsie van die tande word **Zymafluor®** deur die bloedstroom gedra tot by die ontwikkelende tande en maak op dié manier voldoende fluoride ring moontlik. Na erupsie neem die tande fluoried op deur direkte kontak met die fluoried wat in die speeksel is. **Zymafluor®** tablette behoort dus nie heel ingesluk te word nie maar moet toegelaat word om stadig in die mond op te los.

AANWYSINGS
Voorkoming van tandbederf.
Die toediening van **Zymafluor®** word slegs vir die voorkoming van tandbederf aanbeveel, en behoort oorweeg te word waar watervoorrade 'n tekort aan fluoried het.
Spesiale opmerking: daar is geen oortuigende bewyse dat fluoried, van enige bron, die vorming van tandbederf verminder nadat die permanente tande gevorm het nie (gewoonlik op 14 jarige ouderdom).

KONTRA-INDIKASIES
Zymafluor® word teenaangedui by niersiektes.
Hipersensitiwiteit teenoor natriumfluoried.
Alvorens die fluoriedkonsentrasie in die drinkwater voorraad bekend is, behoort **Zymafluor®** nie gebruik te word nie.
Gebruik moet veral vermy word in omgewings waar fluoridasie in die vorm van byvoeging van fluoried by tafelsout of die drinkwater voorraad beoefen word.

WAARSKUWINGS
Indien die water meer as 0,7 mg/l fluoried bevat, word aanvulling nie aanbeveel nie.
Om oordosering te verhoed, behoort die inname van fluoried deur ander bronne, byvoorbeeld deur die dieet of fluoried tandepasta, in ag geneem te word.
Bevat sorbitol, en mag 'n lakserende effek hê. Pasiënte met die seldsame oorerflike toestand van sorbitol-,/ maltitol-,/laktitol intoleransie, moet nie **Zymafluor®** neem nie.

DOSIS EN GEBRUIKSAANWYSINGS
Indien nie anders voorgeskryf deur 'n dokter of 'n tandarts nie, word die volgende doserings aanbeveel:

Ouderdom	*0 tot 2 jaar*	*2 tot 4 jaar*	*4 tot 14 jaar en ouer*
Drink water wat minder as 0,3 mg/l fluoried bevat	1 tablet of 4 druppels daagliks	2 tablette of 8 druppels daagliks	4 tablette of 16 druppels daagliks
Drink water wat 0,3 tot 0,7 mg/l fluoried bevat	Nul	1 tablet of 4 druppels daagliks	2 tablette of 8 druppels daagliks
Drink water wat meer as 0,7 mg/l in fluoried bevat	Nul	Nul	Nul

Toediening behoort in die vroeë kinderjare begin te word. Vier druppels of een 0,25 mg tablet (wat fyn gedruk en in water opgelos behoort te word) behoort by 'n bottel (wat nie melk bevat nie) of 'n soliede maaltyd of alleen toegedien te word.
Sodra die ouderdom van die kind dit toelaat, moet **Zymafluor®** tablette nie meer gesluk word nie, maar stadig in die mond gesuig te word, tussen die wang en tandvleis, soms aan die linker- en soms aan die regterkant. Dit is die beste om die tablette in die aand voor slaaptyd te neem, net nadat die tande geborsel is. Dit verseker dat hoë fluoriedkonsentrasies vir 'n langer tydperk in die mond gehandhaaf kan word.
Raadpleeg asseblief 'n Tandarts, Apteker, Geneesheer of Mediese Beampte om te bepaal of **Zymafluor®** aanvulling nodig is.

NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Die vernaamste manifestasies of tekens van 'n chroniese inname van 'n oormatige hoeveelheid fluoried is gespikkelde tandemalje en osteosklerose ('n verskynsel waarby die digtheid en die verkalking van bene toeneem). Kliniese tekens is pynlike gewrigte, styfheid, beperkte beweging, en in erge gevalle gebreklike misvormdheid.
Die aanbevole dosis moet nie oorskry word nie. Hou buite die bereik van jong kinders.

INTERAKSIES
Die absorpsie van fluoried word geïnhibeer deur kalsium, magnesium of aluminium. **Zymafluor®** behoort daarom nie saam met melk en suiwelprodukte of teensuurmiddels wat kalsium, aluminium of magnesiumsoute bevat, toegedien te word nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
In akute vergiftiging is mondelikse natriumfluoried bytend, omdat die hidrofluoriesesuur vorm in die maag.
Die aanvanklike simptome is die gevolg van die plaaslike werking van fluoried op die slymvlies van die spysverteringskanaal. Die inname van meer as 250 mg natriumfluoried kan dikwels speeksel afskeiding, naarheid, buikpyn, braking en diarree veroorsaak. (L.W. dit is amper 450 **Zymafluor®** tablette of 1800 druppels). Sistemiese simptome is afwisselend en ernstig.
Groot dosisse veroorsaak dors, perspirasie, verlamming, spierswakheid en kloniese konvulsies, gevolg deur respiratoriese- en hartversaking; nierversaking kan voorkom; dood kan binne 2 tot 4 uur intree.
Die pasiënt toon tekens van toenemende geïrriteerdheid van die senustelsel, insluitende parestesieë, 'n positiewe Chvostek teken, hiperaktiewe reflekse, toniese en kloniese konvulsies.
Metaboliese en elektrolitiese versteurings mag voorkom. Hipokal semie en hipoglukemie word dikwels deur die laboratorium toetse getoon. Die tekens kan vir etlike ure vertraag word. Pyn in verskillende spiergroepe kan voorkom. Die bloeddruk daal, vermoedelik as gevolg van die sentrale vasomotoriese depressie asook 'n direkte toksiese werking op die hartspier.
Die respiratoriese sentrum word eers gestimuleer en later onderdruk.
Die fatale natriumfluoried dosis vir volwassenes is ongeveer 5 tot 10 g, terwyl ernstige vergiftiging na mondelikse dosisse van minder as 1 g aangemeld is. By kinders kan 0,5 g natrium fluoried fataal wees (L.W. dit is ongeveer 900 **Zymafluor®** tablette of 3600 druppels). Okulêre skade is ook aangemeld.

BEHANDELING
Tree sonder versuim met u naaste hospitaal in verbinding.
Behandeling is simptomaties en ondersteunend.
Die beginsels van behandeling is soos volg:
1. Handel vinnig.
2. By akute vergiftiging, ledig die maag deur aspirasie en spoeling met kalkwater of 'n 1 % oplossing van kalsiumchloried of 'n ander kalsiumsout.
3. Kalsiumglukonaat inspuiting, 10 ml van 'n 10 % oplossing, kan binneaars toegedien word om konvulsies te beheer en kan 4 tot 6 uurliks herhaal word indien nodig.
4. Morfien of petidien kan ingespuit word indien nodig om koliek te beheer.
5. Die sirkulasie moet in stand gehou word met infusies van toepaslike elektrolietoplossings.
6. Dit kan nodig wees om asemhaling te onder steun.
7. Hemodialise is gebruik.
8. Was braaksel, ontlasting en uriene dadelik af om eksterne velirritasie te voorkom.

IDENTIFIKASIE
Tablette: Wit, ronde, bikonveks tablet met 'n deursnee van ongeveer 4 mm en 'n dikte van ongeveer 2,6 mm.
Druppels: Helder, kleurlose en reuklose oplossing.

AANBIEDING
Tablette: Plastiek houers met 150 en 400 tablette.
Druppels: Plastiek houers wat 20 ml bevat.

BERGINGSAANWYSINGS
Bewaar by of onder 25 °C. Die houer moet dig toegehou word. **HOU BUITE BEREIK VAN KINDERS.**

REGISTRASIE NOMMERS
Tablette: E/24/728
Druppels: Y/24/394

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
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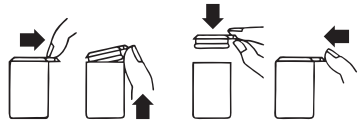

Zymafluor® Tablette
Namibië: Reg. Nr.: 90/24/00683; Skedule 1

Zymafluor® Druppels
Namibië: Reg. Nr.: 10/24/0513; Skedule 1

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