SCHEDULING STATUS:
S3

PROPRIETARY NAME AND DOSAGE FORM:
RISEDRONATE 35 BIOTECH film-coated Tablets

COMPOSITION:
Each RISEDRONATE 35 BIOTECH Tablet contains: 35 mg Monosodium Risedronate hemipentahydrate equivalent to 35 mg risedronate sodium as the active pharmaceutical ingredient.
The inactive pharmaceutical ingredients are: crospovidone, lactose monohydrate (Flowlac 100), microcrystalline cellulose (PH 200), magnesium stearate and opadry orange.
Contains lactose.

PHARMACOLOGICAL CLASSIFICATION:
A 3.2 Connective tissue medicines, non-hormonal preparation

PHARMACOLOGICAL ACTION:
Pharmacodynamics
Risedronate sodium is a pyridinyl bisphosphonate that binds to bone hydroxyapatite and inhibits osteoclast-mediated bone resorption, while bone formation is preserved.
Pharmacokinetics
Absorption:
Risedronate sodium is poorly absorbed after oral administration. Absorption is reduced by food, especially by products containing calcium or other polyvalent cations. The mean bioavailability is 0,63 % in the fasting state, and is reduced by significantly when risedronate sodium is administered with food.
Distribution:
Human plasma protein binding of the drug is about 24 %.
Metabolism:
There is no evidence of systemic metabolism of risedronate sodium.
Elimination:
Approximately half of the absorbed dose is excreted in the urine within 24 hours; the remainder is sequestered to bone for a prolonged period.
Mean renal clearance is 105 ml/min and mean total clearance is 122 ml/min, with the difference primarily reflecting non-renal clearance or clearance due to adsorption to the bone. The renal clearance is not concentration dependent and there is a linear relationship between renal clearance and creatinine clearance. Unabsorbed risedronate sodium is eliminated unchanged in the faeces.

INDICATIONS:
Treatment of osteoporosis in postmenopausal women in combination with calcium 500 to 1000 mg per day. Additional administration of vitamin D should be considered when deficiency might be suspected.

CONTRA-INDICATIONS:
Known hypersensitivity to any ingredient of RISEDRONATE 35 BIOTECH.
Hypocalcaemia (see SIDE EFFECTS AND SPECIAL PRECAUTIONS.)
Severe renal impairment: creatinine clearance < 30 ml/min (see SPECIAL PRECAUTIONS).

WARNINGS:
The most frequent adverse effects during RISEDRONATE 35 BIOTECH therapy are upper gastrointestinal disturbances including dysphagia, oesophagitis, abdominal pain, nausea and vomiting, and diarrhoea or constipation.
Prescribers should therefore emphasise the importance of adherence to the dosing instructions to these patients and therapy should be given with care or avoided if acute upper gastrointestinal inflammation is present.
In order to facilitate delivery to the stomach and minimise the possibility of gastrointestinal adverse effects, patients should take RISEDRONATE 35 BIOTECH whole with a full glass of plain water while in an upright position (standing or sitting) and should avoid lying down for 30 minutes after taking this medication.
Caution should therefore also be exercised in patients who are unable to stand or sit upright for at least 30 minutes.
Patients who experience symptoms such as new or worsening heartburn, pain on swallowing, retrosternal pain, ocular pain or vision loss while taking RISEDRONATE 35 BIOTECH should discontinue the medicine and seek medical attention.

INTERACTIONS:
Absorption of RISEDRONATE 35 BIOTECH is decreased by food, drinks (other than plain water) and other products such as mineral supplements containing aluminium, calcium, iron or magnesium, including antacids and some osmotic laxatives (see SPECIAL PRECAUTIONS).
The use of RISEDRONATE 35 BIOTECH with aspirin and NSAIDs may result in an increased incidence of gastrointestinal or renal adverse effects. There may be additive hypoglycaemic effects with aminoglycosides.

PREGNANCY AND LACTATION:
The safety of RISEDRONATE 35 BIOTECH in pregnant and lactating women has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Adults:
It is important to take RISEDRONATE 35 BIOTECH only as directed.
The recommended dose is one 35 mg tablet orally, once a week.
The tablet should be taken on the same day each week.
Food, drinks (other than plain water) and other products containing polyvalent cations (such as aluminium, calcium, iron or magnesium) decrease the absorption of RISEDRONATE 35 BIOTECH and should not be taken at the same time.
Therefore, RISEDRONATE 35 BIOTECH should be taken either, at least 30 minutes before the first food, or other medicinal product, or drink (other than plain water) of the day or, at least 2 hours away from food or drink at any other time of the day and at least 30 minutes before going to bed.
Patients should be instructed that if a dose is missed, one RISEDRONATE 35 BIOTECH tablet should be taken on the day that the tablet is remembered. Patients should then return to taking one tablet once a week on the day the tablet is normally taken. Two tablets should not be taken on the same day.
The tablets must be swallowed whole and not sucked or chewed.
Patients should take RISEDRONATE 35 BIOTECH while in an upright position (standing or sitting) with a glass of plain water (≥120 ml) to aid delivery to the stomach. Patients should not lie down for 30 minutes after taking the tablet (see SPECIAL PRECAUTIONS).
Elderly:
No dosage adjustment is necessary since bioavailability and disposition are similar in elderly (> 60 years of age) and younger subjects.
Renal impairment:
No dosage adjustment is necessary in patients with creatinine clearance ≥ 30 ml/min. RISEDRONATE 35 BIOTECH is not recommended in patients with severe renal impairment (creatinine clearance < 30 ml/min).
Children:
Safety and efficacy of RISEDRONATE 35 BIOTECH have not been established in children and growing adolescents.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
Blood and the lymphatic system disorders
Less frequent: Leucopenia.
Immune system disorders
Less frequent: Hypersensitivity and skin reactions, including angioedema.
Nervous system disorders
Frequent: Headache.
Eye disorders
Less frequent: Uveitis, iritis, scleritis, episcleritis, optic neuritis.
Gastrointestinal disorders
Frequent: Dyspepsia, nausea, vomiting, abdominal pain, constipation, diarrhoea.
Less frequent: Oesophagitis, oesophageal ulcers or erosions, dysphagia, oesophageal stricture, peptic ulceration, gastritis, glossitis, duedenitis
Hepato-biliary disorders
Less frequent: Abnormal liver function tests.
Skin and subcutaneous tissue disorders
Less frequent: Generalised rash, bullous skin reactions (some severe) and pruritus.
Musculoskeletal, connective tissue and bone disorders
Frequent: Musculoskeletal pain, arthralgia,
Frequency unknown: Osteonecrosis of the jaw
Investigations
The following side effects have been reported and the frequencies are unknown:
Hypocalcaemia and hypophosphataemia.
Special precautions:
Absorption of RISEDRONATE 35 BIOTECH is decreased by food, drinks (other than plain water) and other products containing aluminium, calcium, iron or magnesium, including antacids and mineral supplements and some osmotic laxatives should not be taken at the same time.
Therefore, to achieve the proven benefits of RISEDRONATE 35 BIOTECH, patients should take the tablet either, at least 30 minutes before the first food, medicinal product or drink (other than plain water) of the day or, at least 2 hours away from food or drink at any other time of the day. Hypocalcaemia and other disturbances of bone and mineral metabolism should be effectively treated before starting RISEDRONATE 35 BIOTECH therapy.
There may be additive hypoglycaemic effects with aminoglycosides.RISEDRONATE 35 BIOTECH therapy can exacerbate existing gastrointestinal disorders.
Patients should consult their doctor if they develop symptoms of oesophageal disease. In patients who have a history of oesophageal disorders which delay oesophageal transit or emptying e.g. stricture or achalasia, RISEDRONATE 35 BIOTECH should be used with special caution.
Prescribers should therefore emphasise the importance of following the dosing instructions (see DOSAGE AND DIRECTIONS FOR USE).
As the clinical benefits may be compromised caution should be used in patients who are unable to stay in the upright position for at least 30 minutes after taking the tablet.
RISEDRONATE 35 BIOTECH is not recommended in patients with severe renal impairment (creatinine clearance < 30 ml/min).
Osteonecrosis of the jaw generally associated with tooth extraction and/or local infection (including osteomyelitis) has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates such as RISEDRONATE 35 BIOTECH.
A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates, such as RISEDRONATE 35 BIOTECH in patients with concomitant risk factors (e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene).
While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonates therapy, such as RISEDRONATE 35 BIOTECH, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonates treatment reduces the risk of osteonecrosis of the jaw.
Clinical judgment of the treating doctor should guide the management plan of each patient based on individual benefit/risk assessment.
Important information about some of the ingredients of RISEDRONATE 35 BIOTECH:
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption should not take RISEDRONATE 35 BIOTECH.
Driving and using machinery:
RISEDRONATE 35 BIOTECH may impair the mental and/or physical ability required for performing potentially hazardous tasks such as driving a car or operating machinery.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
Symptoms of hypocalcaemia may occur in some patients. Standard procedures for treatment of hypocalcaemia should be followed.
Milk or antacids containing magnesium, calcium or aluminium should be given to bind RISEDRONATE 35 BIOTECH and minimise absorption. In cases of substantial overdose, gastric lavage may be considered to remove unabsorbed medicine.

IDENTIFICATION:
RISEDRONATE 35 BIOTECH: Orange, oval, biconvex, film-coated tablet, encoded 35 on one side, approximately 11,6 X 5,8 mm in size.

PRESENTATION:
RISEDRONATE 35 BIOTECH: White, HDPE containers with white tamper-evident screw caps containing 4 tablets or transparent PVC/ Al foil blister packs containing 4 tablets.
The blister strips are packed in the outer cardboard carton box.

STORAGE INSTRUCTIONS:
Store at or below 25 °C in the original packing until intended for use. Protect from moisture.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
43/3.2/1158

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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HANDELSNAAM EN DOSEERVORM:
RISEDRONATE 35 BIOTECH filmbedekte tablette.

SAMESTELLING:
Elke RISEDRONATE 35 BIOTECH tablet bevat: 35 mg mononatriumrisedronaat hemipenta-hidraat ekwivalent aan 35 mg risedronaatnatrium as die aktiewe farmaseutiese bestanddeel.
Die onaktiewe farmaseutiese bestanddele is: krospovidoon, laktosemonohidraat (Flowlac 100), mikrokristallyne sellulose (PH 200), magnesiumstearaat en opadry oranje.
Bevat laktose.

FARMAKOLOGIESE KLASSIFIKASIE:
A 3.2 Bindweefselmedisyne, nie-hormonale preparate.

FARMAKOLOGIESE WERKING:
Farmakodinamika
Risedronaatnatrium is 'n piridinielbifosfaat wat aan hidroksiapatiet van been bind en osteoklastgemedieerde beenresorpsie inhibeer, terwyl beenformasie behoue bly.
Farmakokinetika
Absorpsie:
Risedronaatnatrium word swak na orale toediening geabsorbeer. Die absorpsie word deur inname van voedsel, veral deur produkte wat kalsium of ander polivalente katione bevat, verminder. Die gemiddelde biobeskikbaarheid van risedronaatnatrium is 0,63 % tydens vasting en neem aansienlik af wanneer dit saam met voedsel toegedien word.
Verspreiding:
Menslike plasmaproteïenbinding van die middel is ongeveer 24 %.
Metabolisme:
Daar bestaan geen bewys van die sistemiese metabolisme van risedronaatnatrium nie.
Eliminasie:
Ongeveer die helfte van die geabsorbeerde dosis word binne 24 uur in die urien uitgeskei; die res word oor 'n lang periode na die been versprei.
Die gemiddelde nieropruiming is 105 ml/min en die gemiddelde totale opruiming is 122 ml/min. Hierdie verskil dui hoofsaaklik op nie-renale opruiming of opruiming weens adsorpsie aan die been. Nieropruiming is nie van die konsentrasie afhanklik nie en daar bestaan 'n lineêre verwantskap tussen nieropruiming en kreatinienopruiming. Ongeabsorbeerde risedronaatnatrium word onveranderd in die feses uitgeskei.

INDIKASIES:
Behandeling van osteoporose in postmenopousale vroue in kombinasie met kalsium 500 tot 1000 mg per dag. Addisionele toediening van vitamien D behoort oorweeg te word wanneer 'n tekort vermoed word.

KONTRA-INDIKASIES:
Bekende hipersensitiwiteit teen enige van die bestanddele van RISEDRONATE 35 BIOTECH
Hipokalsemie (kyk NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS).
Erge nierinkorting: kreatinienopruiming < 30 ml/min (kyk SPESIALE VOORSORGMAATREËLS).

WAARSKUWINGS:
Die mees dikwelste newe-effek tydens terapie met RISEDRONATE 35 BIOTECH is boonste gastroïntestinale steurnisse, insluitende disfagie, esofagitis, buikpyn, naarheid en braking, en diarree of hardlywigheid. Die voorskrywer behoort daarom die belang van nakoming van die dosisaanbevelings aan hierdie pasiënte te beklemtoon, en terapie moet met sorg geskied of vermy word indien akute boonste gastroïntestinale inflammasie teenwoordig is.
Om lewering na die maag te vergemaklik en om die moontlikheid van gastroïntestinale newe-effekte tot 'n minimum te beperk, behoort pasiënte RISEDRONATE 35 BIOTECH met 'n glas skoon water te neem terwyl hulle in 'n regop posisie is (staande of sittend) en behoort hulle vir 30 minute nadat die medisyne geneem is, nie te gaan lê nie. Sorg behoort daarom aan die dag gelê te word in pasiënte wat nie in staat is om vir 30 minute regop te staan of te sit nie.
Pasiënte wat simptome soos nuwe of toenemende sooibrand, pyn met sluk, retrosternale pyn, oogpyn of gesigsverlies ondervind terwyl hulle RISEDRONATE 35 BIOTECH gebruik, behoort die medisyne te staak en mediese advies in te win.

INTERAKSIES:
Die absorpsie van RISEDRONATE 35 BIOTECH word deur voedsel, vloeistof (behalwe skoon water) en ander produkte soos minerale supplemente wat aluminium, kalsium, yster of magnesium bevat, insluitende teensuurmiddels en sommige osmotiese lakseermiddels, verminder (kyk SPESIALE VOORSORGMAATREËLS).
Die gebruik van RISEDRONATE 35 BIOTECH saam met aspirien en NSAIM mag tot 'n toename in die voorkoms van gastroïntestinale en renale newe-effekte lei. Saam met aminoglikosiede mag daar bykomende hipoglukemiese effekte wees.

SWANGERSKAP EN BORSVOEDING:
Die veiligheid van RISEDRONATE 35 BIOTECH in swanger en lakterende vroue is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes:
Dit is belangrik om RISEDRONATE 35 BIOTECH slegs soos aangewys te gebruik.
Die aanbevole dosis is een 35 mg tablet oraal, een keer per week.
Die tablet behoort op dieselfde dag van elke week geneem te word.
Voedsel, vloeistof (behalwe skoon water) en ander produkte wat polivalente katione (soos aluminium, kalsium, yster of magnesium) bevat, verminder die absorpsie van RISEDRONATE 35 BIOTECH en behoort nie op dieselfde tyd geneem te word nie.
Daarom behoort RISEDRONATE 35 BIOTECH ten minste 30 minute voor die eerste maaltyd, of enige medisinale produk of vloeistof (behalwe skoon water) van die dag, of ten minste 2 ure na of voor voedsel of vloeistof op enige ander tyd van die dag en ten minste 30 minute voor slapenstyd geneem te word.
Pasiënte behoort aangesê te word dat indien 'n dosis oorgeslaan word, een RISEDRONATE 35 BIOTECH tablet op die dag wat dit onthou word, te neem. Pasiënte behoort dan weer een tablet een keer per week te neem op die dag wat dit gewoonlik geneem word. Moenie twee tablette op dieselfde dag neem nie.
Die tablette moet heel geneem word en nie gesuig of gekou word nie.
Pasiënte behoort RISEDRONATE 35 BIOTECH in 'n regop posisie (staande of sittend) met 'n glas skoon water (≥ 120 ml) te neem om lewering na die maag te bewerkstellig. Pasiënte behoort vir ten minste 30 minute nadat die tablet geneem is, nie te gaan lê nie (kyk SPESIALE VOORSORGMAATREËLS).
Bejaardes:
Geen dosisaanpassing is nodig nie aangesien die biobeskikbaarheid en disposisie in bejaardes (> 60 jaar oud) en jonger individue eenders is.
Nierinkorting:
Geen dosisaanpassing is in pasiënte met kreatinienopruiming ≥30 ml/min nodig nie. RISEDRONATE 35 BIOTECH word nie in pasiënte met erge nierinkorting (kreatinienopruiming < 30 ml/min) aanbeveel nie.
Kinders:
Die veiligheid en effektiwiteit is nie in kinders en groeiende adolessente vasgestel nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:
Afwykings van die bloed- en limfsisteem
Minder dikwels: Leukopenie.
Afwykings van die immuunstelsel
Minder dikwels: Hipersensitiwiteit en velreaksies, insluitende angioëdeem.
Afwykings van die senuweestelsel
Dikwels: Hoofpyn.
Oogafwykings
Minder dikwels: Uveïtis, iritis, skleritis, episkleritis, optiese neuritis.
Gastroïntestinale afwykings
Dikwels: Dispepsie, naarheid, braking, buikpyn, hardlywigheid, diarree.
Minder dikwels: Esofagitis, esofageale ulkusse of erosies, disfagie, esofageale vernouing, maagulkus, gastritis, glossitis, duodenitis.
Hepatobileêre afwykings
Minder dikwels: Abnormale lewerfunksietoetse.
Afwykings van die vel en subkutane weefsel
Minder dikwels: Algemene veluitslag, bulleuse velreaksies (soms erg) en pruritus.
Muskuloskeletale, bindweefsel- en beenafwykings
Dikwels: Muskuloskeletale pyn, artralgie.
Frekwensie onbekend: Osteonekrose van die kaak.
Ondersoeke
Die volgende newe-effekte is gerapporteer en die frekwensie is onbekend:
Hipokalsemie en hipofosfatemie.
Spesiale Voorsorgmaatreëls:
Die absorpsie van RISEDRONATE 35 BIOTECH word deur voedsel, vloeistof (behalwe skoon water) en ander produkte wat aluminium, kalsium, yster of magnesium bevat, insluitende teensuurmiddels en minerale supplemente verminder en sommige osmotiese lakseermiddels behoort nie op dieselfde tyd geneem moet word nie.
Daarom behoort pasiënte, om die bewese voordele van RISEDRONATE 35 BIOTECH te kry, die tablet ten minste 30 minute voor die eerste maaltyd, medisinale produk of vloeistof (behalwe skoon water) van die dag, of ten minste 2 ure voor of na voedsel of vloeistof op enige ander tyd van die dag te neem.
Hipokalsemie en ander afwykings van been en minerale metabolisme behoort, voordat daar met RISEDRONATE 35 BIOTECH terapie begin word, effektief behandel te word.
Daar mag bykomende hipoglukemiese effekte met aminoglikosiede voorkom. Terapie met RISEDRONATE 35 BIOTECH mag reeds bestaande gastroïntestinale afwykings vererger.
Pasiënte behoort hul dokter te raadpleeg indien hulle simptome van esofageale siekte ontwikkel. In pasiënte met 'n geskiedenis van esofageale afwykings wat esofageale deurgang of lediging vertraag bv. vernouing of achalasie, behoort RISEDRONATE 35 BIOTECH met ekstra sorg gebruik te word.
Voorskrywers behoort daarom die belang van die nakoming van die doseringsinstruksies te beklemtoon (kyk DOSIS EN GEBRUIKSAANWYSINGS).
Aangesien kliniese voordele in gedrang mag kom, behoort sorg aan die dag gelê te word in pasiënte wat nie in staat is om vir ten minste 30 minute regop te bly nadat die tablet geneem is nie.
RISEDRONATE 35 BIOTECH word nie aanbeveel in pasiënte met erge nierinkorting (kreatinienopruiming < 30 ml/min) nie.
Osteonekrose van die kaak wat algemeen met tandekstraksie en/of plaaslike infeksie gepaard gaan (insluitende osteomiëlitis) is in pasiënte met kanker wat behandelingsregime, insluitende hoofsaaklik intraveneus toegediende bisfosfonate ontvang, gerapporteer. Baie van hierdie pasiënte het ook chemoterapie en kortikosteroïede ontvang. Osteonekrose van die kaak is ook in pasiënte met osteoporose wat orale bisfosfonate soos RISEDRONATE 35 BIOTECH ontvang, gerapporteer.
'n Tandheelkundige ondersoek met die gepaste voorkomende tandheelkunde behoort voor behandeling met bisfosfonate soos RISEDRONATE 35 BIOTECH, in pasiënte met meegaande risikofaktore (bv. kanker, chemoterapie, radioterapie, kortikosteroïede, swak mondhigiëne) oorweeg te word.
Gedurende behandeling behoort hierdie pasiënte ingrypende tandheelkundige prosedures, indien moontlik te vermy. Vir pasiënte wat osteonekrose van die kaak ontwikkel terwyl hulle op bisfosfonaatterapie, soos RISEDRONATE 35 BIOTECH is, mag tandheelkundige chirurgie die kondisie vererger. Vir pasiënte wat tandheelkundige prosedures benodig, bestaan daar geen beskikbare data wat daarop dui dat die staking van bisfosfonaatbehandeling die risiko van osteonekrose van die kaak verminder nie.
Die kliniese beslissing van die behandelende dokter behoort die bestuursplan vir elke pasiënt, gebaseer op die individuele voordeel/risikobepaling te bepaal.
Belangrike inligting oor sommige van die bestanddele van RISEDRONATE 35 BIOTECH:
Pasiënte met skaars oorerflikheidsprobleme van galaktoseïntoleransie, die Lapp laktasetekort of glukose/galaktose wanabsorpsie behoort nie RISEDRONATE 35 BIOTECH te gebruik nie.
Bestuur en die gebruik van masjinerie:
RISEDRONATE 35 BIOTECH mag verstandelike en/of fisiese vermoëns wat nodig is om potensieel gevaarlike take soos om 'n motor te bestuur of om met masjinerie te werk, inkort.

BEKEND SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Simptome van hipokalsemie mag in sommige pasiënte voorkom. Die standaard prosedure vir die behandeling van hipokalsemie behoort gevolg te word.
Melk of teensuurmiddels wat magnesium, kalsium of aluminium bevat behoort toegedien te word om RISEDRONATE 35 BIOTECH te bind en absorpsie tot 'n minimum te beperk. In gevalle van aansienlike oordosering mag maagspoeling oorweeg word om ongeabsorbeerde medisyne te verwyder.

IDENTIFIKASIE:
RISEDRONATE 35 BIOTECH: Oranje, ovaalvormige, bikonvekse, filmbedekte tablet, gemerk met 35 op die een kant, ongeveer 11,6 X 5,8 mm in grootte.
Aanbiedinge:
RISEDRONATE 35 BIOTECH: Wit, HDPE houer met 'n peutervrye skroefdop met 4 tablette, of 'n deursigtige PVC/Al foelie stulpstrokie met 4 tablette.
Die stulpstrokies word in 'n buitenste kartonhouer verpak.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C in die oorspronklike houer tot voor gebruik. Beskerm teen vogtigheid.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
43/3.2/1158

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