

Reference number	Product name	Dosage Form	Active Ingredient/s	Product Uses or Claims	Reason/Remarks	Date of Decision Letter
CC0040/020	UBIT	Tablet	Urea Carbon 13 100mg tablets	For diagnosis of H. Pylori	Product deemed to fall within the second limb of the definition of a medicinal product: The product is intended to be used for medical diagnosis and the product achieves its function through a metabolic action.	13/10/2020
CC0041/2 0	Immunoday Baby	Syrup	Zinc 3 mg (VNR% 30) Vitamin C 67.5 mg (VNR % 84) Echinacea purpurea e.s. tit. 4% 66 mg Turmeric rhizome (Curcuma longa L.) e.f 0.1 ml Blueberry fruit (Vaccinium myrtilus L.) conc juice Aroma Fructose syrup Honey Potassium sorbate	Food supplement of vegetal extracts with Vitamin C and Zinc	Product deemed to fall within the first limb of the definition of a medicinal product: The product which is intended for children contains a high dose of echinacea. This suggests that the use of the product is intended to prevent diseases such as common colds. The HMPC monograph recommends that echinacea should not be used in children under 2 years.	01/12/2020
CC001/21	Men's Foligain Extra Strength Minoxidil Topical Solution USP, 5 %	Liquid medication, Dropper application	Mixodil 5% w/w	To help grow hair in men at least a male at least 18 years old and experiencing gradual hair loss on the top of the scalp.	Product deemed to fall within the second limb of the definition of a medicinal product: The product contains minoxidil a substance found in medicinal products which has a pharmacological action to achieve the intended action,	29/01/2021

<p>CC005/21</p>	<p>FOLIGAIN Advanced Hair Regrowth Treatment Foam for Men with 5% Minoxidil</p>	<p>Foam</p>	<p>Mixodil 5% w/w</p>	<p>Foam treatment to help regrow hair Reactivates hair follicles to stimulate regrowth For men who have a general thinning of hair on the top of the scalp (vertex, as shown below). Painless, clinically proven answer to hair loss in men that works by awakening and revitalizing the scalp area—specifically the deadened hair follicles. It is clinically shown to help prevent hair loss and regrow hair in just a few months.</p>	<p>Product deemed to fall within the second limb of the definition of a medicinal product: The product contains minoxidil a substance found in medicinal products which has a pharmacological action to achieve the intended action,</p>	<p>29/01/2021</p>
<p>CC006/21</p>	<p>FOLIGAIN® Advanced Hair Regrowth Treatment for Men Minoxidil 5% & Trioxidi 5%</p>	<p>Spray</p>	<p>Mixodil 5% w/w Trioxidil 5% w/w</p>	<p>Hair loss solution for men with fine or thinning hair. To revitalize hair follicles and help prevent hair loss. By stimulating the extracellular matrix of the scalp using advanced mechanisms, it helps build the necessary proteins for healthy hair growth and superior hair anchoring, and supports overall scalp health.</p>	<p>Product deemed to fall within the second limb of the definition of a medicinal product: The product contains minoxidil a substance found in medicinal products which has a pharmacological action to achieve the intended action</p>	<p>29/01/2021</p>
<p>CC007/21</p>	<p>FOLIGAIN Advanced Hair Regrowth Styling Gel for Men with 5% Minoxidil</p>	<p>Gel</p>	<p>Minoxidil 5% w/w</p>	<p>Clinically proven to help regrow hair in men while styling hair for a light hold. The innovative pure and potent minoxidil 5% formula stimulates hair follicles for thicker, fuller hair and improves scalp health. For individuals who are suffering from hair thinning , awakens the scalp area—specifically</p>	<p>Product deemed to fall within the second limb of the definition of a medicinal product: The product contains minoxidil a substance found in medicinal products which has a pharmacological action to achieve the intended action,</p>	<p>29/01/2021</p>

				the deadened hair follicles— exerting maximum hair growth on the crown of the head in men		
CC0011/21	FOLIGAIN® Minoxidil 2% Hair Regrowth Treatment for Women 3 Month Supply	Dropper	Minoxidil 5% w/w	Clinically shown to help prevent hair loss and fall, and promote hair regrowth on the scalp area in women by reactivating deadened hair follicles for new growth in just a few months. For women experiencing hereditary hair loss.	Product deemed to fall within the second limb of the definition of a medicinal product: The product contains minoxidil a substance found in medicinal products which has a pharmacological action to achieve the intended action,	29/01/2021
CC0022/2 1	Dettol Liquid / Antiseptic Disinfectant 4.8% w/v (Chloroxylenol)	Liquid	4.8% w/v (Chloroxylenol)	For cuts, bites, abrasions and insect stings. Personal hygiene - for douching, dandruff; and spots and pimples.		23/03/2021
CC0030/21	Dentogen Clove Oil Gel Toothache Pain Relief	Oral Gel	Clove Oil 20.0 w/w	This medicine contains the active ingredient Clove Oil which is a mild analgesic and surface anaesthetic used for the temporary relief of toothache due to a dental cavity	A medicinal product due to its presentation and content – The active ingredient eugenol exhibits mild analgesic and anaesthetic properties	06/09/2021

<p>CC0012/22</p>	<p>Melatonin 5 mg capsules</p>	<p>Capsule</p>	<p>Melatonin 5 mg</p>	<p>As a dietary supplement as a sleep aid for relief of occasional sleeplessness</p>	<p>A medicinal product due to its content – Melatonin with a strength of 2 mg and above is considered to have a pharmacological, immunological or metabolic action. This strength is found in authorised medicinal products e.g. Circadin and Slenyto. These products have been demonstrated to have a pharmacological action and are indicated for the treatment of a medical condition</p>	<p>05/07/2022</p>
<p>CC0027/22</p>	<p>Advancis Extra Cough Relief Kids</p>	<p>Syrup</p>	<p>Echinacea purpurea, Echinacea - 300 mg Angelica archangelica, Angelica - 270 mg Glycyrrhiza glabra, Liquorice - 255 mg Vitamin C - 120 mg</p>	<p>As a dietary supplement as a sleep aid for relief of occasional sleeplessness</p>	<p>A medicinal product due to its presentation – The term ‘cough relief’ in the name of the product implies that the product is to be used for a medicinal purpose</p>	<p>22/09/2022</p>
<p>CC0035/22</p>	<p>Erbalax forte Tablets</p>	<p>Tablet</p>	<p>Per 3 tablets: Cascara Sagrada (Rhamnus purshiana DC.) bark powder 342 mg Frangula ((Rhamnus frangula L.) bark powder 228 mg Senna (Cassia angustifolia Vahl) leaves powder 148 mg Rhubarb (Rheum palmatum L.) rhizome powder 143 mg Senna (Cassia angustifolia Vahl) leaves dry extract</p>	<p>Erbalax Forte tablets is a food supplement based on plant extracts; with Senna, Cascara Sagrada and Rhubarb useful to rebalance gut transit in situations of strong intestinal irregularity. Dandelion assists the body's depurative function, while Fennel, Cloves and Gentian promote digestive process</p>	<p>A medicinal product due to its content – The product contains a number of herbal ingredients either in the form of extracts or in powdered form. Some of the individual components have no food use (example senna) while the majority of the individual components are ingredients which have been used for its laxative effect/effect in the GI tract. The combination of</p>	<p>24/11/2022</p>

			<p>51 mg Dandelion (<i>Taraxacum officinale</i> (L.) Weber ex F.H.Wigg.) root powder</p> <p>51 mg Mallow (<i>Malva sylvestris</i> L.) flowers and leaves dry extract</p> <p>51 mg Fennel (<i>Foeniculum vulgare</i> Mill.) fruits powder</p> <p>46 mg Licorice (<i>Glycyrrhiza glabra</i> L.) root powder</p> <p>34 mg Cloves (<i>Eugenia caryophyllata</i> Thunb.) flower bud powder</p> <p>23 mg Gentian (<i>Gentiana lutea</i> L.) root powder</p> <p>21 mg</p>		<p>ingredients suggests that the product is intended for a laxative effect as mentioned in the technical data sheet. The sennoside content for this product falls within the dosing limits of medicinal products containing senna which ranges from 7.5mg up to 15mg and so a pharmacological effect is available.</p>	
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