

<u>MA (EU) number</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/22/1652/002	Filsuvez	-- ¹	Gel	Cutaneous use	tube (alu)	23.4 g	1 tube
EU/1/22/1652/004	Filsuvez	-- ¹	Gel	Cutaneous use	tube (alu)	23.4 g	10 tubes
EU/1/22/1652/005	Filsuvez	-- ¹	Gel	Cutaneous use	tube (alu)	23.4 g	30 tubes

--¹ 1 g of gel contains 100 mg of extract (as dry extract, refined) from *Betula pendula* Roth, *Betula pubescens* Ehrh. as well as hybrids of both species, cortex (equivalent to 0.5-1.0 g birch bark), including 84-95 mg triterpenes calculated as the sum of betulin, betulinic acid, erythrodiol, lupeol and oleanolic acid. Extraction solvent: n-Heptane.