



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 October 2020  
EMA/541185/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: haemophilus type b conjugate vaccines

Procedure no.: PSUSA/00001584/202002

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Act-HIB 10 microgram/0,5 ml poeder en oplosmiddel voor oplossing voor injectie Geconjugeerd Haemophilus influenzae type b vaccin	not available	RVG 17508	SANOFI PASTEUR EUROPE	NL
Act-HIB 10 microgram/0,5 ml, poeder en oplosmiddel voor oplossing voor injectie Geconjugeerd Haemophilus influenzae type b vaccin	not available	BE158724	SANOFI PASTEUR EUROPE	BE
Act-HIB 10 microgrammes/0,5 ml, poudre et solvant pour solution injectable Vaccin conjugué de l' Haemophilus influenzae type b	not available	BE158724	SANOFI PASTEUR EUROPE	BE
ACT-HIB 10 microgrammes/0,5 ml, poudre et solvant pour solution injectable en seringue préremplie Vaccin conjugué de l' Haemophilus type b	not available	NL 17 742	SANOFI PASTEUR	FR

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Act-HIB 10 microgrammes/0,5 ml, poudre et solvant pour solution injectable Vaccin conjugué de l' Haemophilus influenzae type b	not available	2002127082	SANOFI PASTEUR EUROPE	LU
Act-HIB 10 micrograms/0.5 mL, powder and solvent for solution for injection in pre-filled syringe Haemophilus type b conjugate vaccine	not available	14308	SANOFI PASTEUR	CY
Act-HIB 10 mikrogram/0,5 ml pulver och vätska till injektionsvätska, lösning Haemophilus influenzae - vaccin, typ b (konjugerat)	not available	10725	SANOFI PASTEUR EUROPE	FI
Act-HIB 10 mikrogram/0,5 ml.Pulver og væske til injeksjonsvæske, oppløsning Vaksine mot Haemophilus type b, konjugert	not available	7985	SANOFI PASTEUR EUROPE	NO
Act-HIB 10 Mikrogramm/0,5 ml, Pulver und Lösungsmittel zur Herstellung einer	not available	BE158724	SANOFI PASTEUR EUROPE	BE

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Injektionslösung Konjugatimpfstoff gegen Haemophilus influenzae Typ b				
Act-HIB 10 Mikrogramm/0,5 ml, Pulver und Lösungsmittel zur Herstellung einer Injektionslösung Konjugatimpfstoff gegen Haemophilus influenzae Typ b	not available	2002127082	SANOFI PASTEUR EUROPE	LU
Act-HIB 10 µg/0,5 ml pó e solvente para solução injectável Vacina conjugada contra o Haemophilus influenzae tipo b (conjugada com proteína tetânica)	not available	3000189	SANOFI PASTEUR EUROPE	PT
ACT-HIB Polvere e solvente per soluzione iniettabile Vaccino Haemophilus influenzae di tipo b coniugato al tossoido tetanico	not available	028473015	SANOFI PASTEUR EUROPE	IT
ACT-HIB polvo y disolvente para solución inyectable Vacuna de polisacárido de	not available	60.411	SANOFI PASTEUR EUROPE	ES

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Haemophilus influenzae tipo b conjugado a proteína del tétanos				
Act-HIB pulver och vätska till injektionsvätska, lösning Vaccin mot Haemophilus influenzae typ b, konjugerat.	not available	11584	SANOPI PASTEUR EUROPE	SE
Act-HIB Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension	not available	2-00101	SANOPI PASTEUR EUROPE	AT
Act-HiB Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension Haemophilus Typ b- Impfstoff (konjugiert)	not available	482A/91	SANOPI PASTEUR EUROPE	DE
Act-HIB stungulyfsstofn og leysir, lausn Samtengt bóluefni gegn Haemophilus influenzae af stofni b	not available	910203	SANOPI PASTEUR EUROPE	IS
Act-HIB, 10 mikrogramów/0,5 ml, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań Szczepionka przeciw	not available	R/3468	SANOPI PASTEUR	PL

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haemophilus typ b, skoniugowana				
Act-HIB,10 mikrog/0,5 ml injektiokuiva-aine ja liuotin, liuosta varten Haemophilus influenzae tyyppi b (Hib) -rokote (konjugoitu)	not available	10725	SANOFI PASTEUR EUROPE	FI
ACT-HIB® Συνεξευγμένο εμβόλιο Haemophilus influenzae τύπου b	not available	60813/6-10-2015 & 63436/21-09-2016 & 65106/27-05-2019	SANOFI PASTEUR EUROPE	GR
HIBERIX - 10 microgrammes/0,5 ml Poudre et solvant pour solution injectable	not available	BE230151	GLAXOSMITHKLINE BIOLOGICALS S.A.	BE
HIBERIX 10 µg/0,5 ml Pó e solvente para solução injectável Vacina contra Haemophilus influenzae tipo b (Hib)	not available	2751881	SMITH KLINE & FRENCH PORTUGUESA-PRODUTOS FARMACEUTICOS LDA	PT
HIBERIX 10 µg/0,5 ml Pó e solvente para solução injetável Vacina contra Haemophilus influenzae tipo b (Hib)	not available	5571914	SMITH KLINE & FRENCH PORTUGUESA-PRODUTOS FARMACEUTICOS LDA	PT

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Hiberix Polvere e solvente per soluzione iniettabile per uso intramuscolare Vaccino Haemophilus influenzae di tipo b coniugato al tossoide tetanico	not available	031902024	GLAXOSMITHKLINE S.P.A.	IT
Hiberix Polvere e solvente per soluzione iniettabile per uso intramuscolare Vaccino Haemophilus influenzae di tipo b coniugato al tossoide tetanico	not available	031902012	GLAXOSMITHKLINE S.P.A.	IT
Hiberix polvo y disolvente para solución inyectable Vacuna conjugada de Haemophilus influenzae tipo b	not available	61.834	GLAXOSMITHKLINE, S.A.	ES
Hiberix Vaccine Haemophilus influenzae type b (Hib) vaccine	not available	PL 10592/0120	SMITHKLINE BEECHAM PLC	UK
Hiberix Vaccine Haemophilus influenzae type b (Hib) vaccine.	not available	MA 170/01201	GLAXOSMITHKLINE BIOLOGICALS S.A.	MT
Hiberix Vakcína proti Haemophilus influenzae typu b Prášek a	not available	59/1287/97-C	GLAXOSMITHKLINE BIOLOGICALS S.A.	CZ

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rozpouštědlo pro injekční roztok				
Hiberix, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań Vaccinum haemophili stirpi b coniugatum Szczepionka przeciwko zakażeniom haemophilus typ b, skoniugowana	not available	R/7048	GLAXOSMITHKLINE BIOLOGICALS S.A.	PL
Hiberix. Haemophilus Type b (Hib) vaccine Powder and Solvent for Solution for Injection	not available	PA1077/027/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Hiberix® Wirkstoff: Haemophilus-influenzae-b-Konjugat-Impfstoff	not available	100A/95	GLAXOSMITHKLINE GMBH & CO. KG	DE
VAXEM Hib sospensione iniettabile in siringa preriempita Vaccino coniugato anti-Haemophilus influenzae tipo b	IT/H/0122/001	028780056	GSK VACCINES S.R.L.	IT
VAXEM Hib sospensione iniettabile Vaccino coniugato anti-	IT/H/0122/001	028780043	GSK VACCINES S.R.L.	IT



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Haemophilus influenzae tipo b				