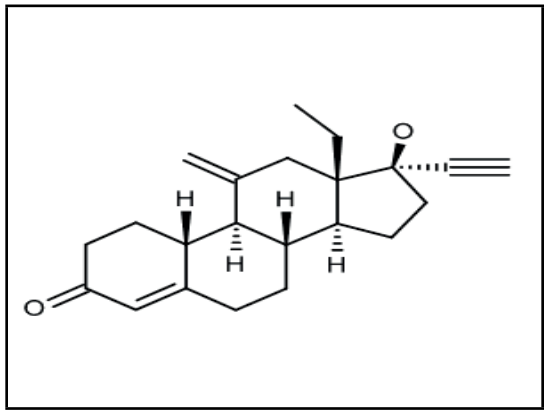
ETONOGESTREL



Leading Products:
IMPLANON

Leading Companies:
MERCK & CO, ORIFARM, ACA MUELLER >>

Leading Diseases:
CONTRACEPTIVE MANAGEMENT

Marketed Indications:
female contraception

R&D Indications:
female contraception

Therapy Name and Code:

Drug Report

Ray Ray
12/06/2016

G3A(Hormonal Contraceptives, Systemic)

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DRUG OVERVIEW

IMPLANON (MERCK & CO)

IMPLANON (etonogestrel implant), a novel, single rod contraceptive delivery system, utilizing etonogestrel in a subdermal implant form to provide sustained-release contraceptive protection for up to three years. It was first launched by Organon (acquired by Schering-Plough, now Merck & Co) in Sweden in 1999, and has since been launched in more than 30 countries worldwide, including Europe, Latin America, Australia, Malaysia, Thailand, Singapore, and South Korea. It was launched in the USA in 2006.

Lifecycle Management: Merck has developed a next-generation version of the product, Implanon NXT. It is a radiopaque version of the product and easier to insert and remove. It was launched in the USA, as Nexplanon, in 2011, when it was also approved in Europe. It is now available as Implanon NXT in Ireland and Australia.

Competition: According to IMS, in 2014, Implanon ranked fifth in the 'Systemic Hormonal Contraceptives' (G3A) class, with a 3.5% market share and sales up by 5%. Merck & Co's NuvaRing (etonogestrel + ethinylestradiol vaginal ring) was in first place, with an 8.7% market share and sales up by 8.3%. Bayer's Mirena (intrauterine levonorgestrel) was in second position, with an 8.4% share, although sales were down by 3.3%. Johnson & Johnson's Ortho Tri-Cy-Lo (ethinylestradiol + norgestimate) was in third place with a 4.6% market share and sales up by 1%.

Sales/Analyst Comment: Global sales of Implanon grew 25% to $502m in 2014 driven by higher demand in the USA. According to a consensus forecast, sales will amount to $556m in 2015 and will increase to $676m by 2019.

Publication Date: 17 Jul 2015

MK 8342 (MERCK & CO)

ETONOGESTREL-RELEASING IUS (MK 8342): Merck & Co is developing MK 8342, an intrauterine system which releases etonogestrel, as a potential contraceptive; phase II trials were ongoing in 2015.

Publication Date: 17 Jul 2015

R&D PROFILE

drug delivery system, implant etonogestrel, Merck & Co

Product Details

Update Date
10 Nov 2011

Drug Names

	Trade Name(s)	DESOPLAN; IMPLANON; IMPLANON NXT; NEXPLANON;
	Generic Name(s)	drug delivery system, implant etonogestrel, Merck & Co; etonogestrel, implant, drug delivery system; etonogestrel (INN) ; etonogestrel (USAN) ;
	Lab Code(s)	ORG 3236;

Latest News

10 November 2011 : On 9 November 2011 Merck & Co announced that NEXPLANON 68 mg, a subdermal etonogestrel implant designed to replace the widely marketed IMPLANON, has been launched in the USA. The system consists of a matrix of ethylene-vinyl-acetate copolymer and continuously delivers a low dose of etonogestrel. This system offers contraceptive protection for a three-year period. NEXPLANON, which contains barium to allow localization on X-ray or CT scan, has a different insertion mechanism from IMPLANON (which does not contain barium). NEXPLANON was approved in the EU in April 2010.

Licensor(s)

Merck & Co

Latest Phase

Marketed

Active Program

No

Indication

female contraception

female genitourinary disease

genitourinary disorder

Action

progestogen

Mode of Administration

implant

Class Description

Hormonal Contraceptives (G3A)

All Other Non-therapeutic Products (V7A)

Company and Country Details

Franchise

	Company	Nationality	Parent Company	Relationship	Licensee Region
	Merck & Co	USA	Merck & Co	Developer	

Country Status

	Phase	Country	Indication
	Marketed	USA	female contraception
	Marketed	South Korea	female contraception
	Marketed	Europe	female contraception
	Marketed	Brazil	female contraception
	Marketed	Australia	female contraception
	Marketed	Chile	female contraception
	Marketed	French West Africa	female contraception
	Marketed	Indonesia	female contraception
	Marketed	Malaysia	female contraception
	Marketed	Thailand	female contraception
	Marketed	Turkey	female contraception
	Phase III	Canada	female contraception
	Phase III	SE Asia	female contraception
	Phase III	South America	female contraception

Chemical and Patent Details

Chemical Name

7alpha-ethinyl-17beta-hydroxy-18-methyl-11-methylen-4-estren-3-one
CAS Number

54048-10-1,etonogestrel

165050-21-5,replaced by 54048-10-1

Patentee

Akzo Nobel
Patent Data

Product (Akzo Nobel): GB 1455270 1976, priority NL 16767 1972. Equivalents identified. Composition: EP 303306 B 1993, priority NL 1868 1987. Equivalents identified.

Commercial Details

Commercial overview
Overview

Merck & Co (formerly Organon) has developed NEXPLANON, a subdermal etonogestrel implant for use as a contraceptive. NEXPLANON is designed to replace the widely marketed IMPLANON. The system consists of a matrix of ethylene-vinyl-acetate copolymer and continuously delivers a low dose of etonogestrel. This system offers contraceptive protection for a three-year period. NEXPLANON, which contains barium to allow localization on X-ray or CT scan, has a different insertion mechanism from IMPLANON (which does not contain barium). IMPLANON was first launched in Sweden in February 1999 and has subsequently been marketed in most countries worldwide. NEXPLENON was approved in the EU in April 2010 and in the USA in the second quarter 2011; NEXPLANON 68 mg was launched in the USA in November 2011. In December 1972, a priority product patent application was filed in the Netherlands by Akzo Nobel (now Merck & Co).

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Regulatory progress
Female contraception

EU

Merck & Co radiopaque version.---Supplemental approval - Apr 2010. Merck & Co has received approval for a radiopaque version of its subdermal etonogestrel implant in the EU for use as a contraceptive device (Merck & Co, OCT 2010).

USA

Merck & Co radiopaque version.---Supplemental filing - S2 2010. A regulatory filing is under review in the USA for a radiopaque version of the etonogestrel implant as a contraceptive device (Merck & Co, OCT 2010).---Supplemental approval - Q2 2011. This barium-containing radiopaque version of the subdermal etonogestrel implant has been approved in the USA, under the trade name NEXPLANON, as a contraceptive device (Merck & Co, JUL 2011).