

# Drug Patent Profiles

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# Make Better Decisions with detailed reports

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- ❖ Invaluable business insights into every crucial aspect of each drug, addressing the vital points necessary to make business decisions.
- ❖ Track loss of patents / generic entry to stay ahead of market changes.
- ❖ Stay on top of patent litigation to prepare for early generic entry.
- ❖ See clinical trial activity to track development of new formulations or new therapeutic indications.

# List of active patents, with their claims

## US Patent 7,500,444

US Patent 7,500,444 protects ADVAIR HFA and FLOVENT HFA.

### Patent Title

Actuation indicator for a dispensing device

### Patent Claim Types

Use;

### Patent Abstract

An actuation indicator that includes a drum sub-assembly, which includes a rotatable actuation indicator wheel, a rocking, ratchet pawl for rotating the indicator wheel in a set direction and a rocking mechanism for the pawl driven by a slipping clutch arrangement, is described. The slipping clutch arrangement includes a slipping clutch spring engaged at one end to a pinion of a rack and pinion assembly and at a second end to the ratchet pawl.



What other drugs does this patent protect?

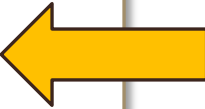


Patent claim types indicate what is protected

# Get intelligence from expired patents

## Expired US Patent Summary for ADVAIR HFA

Dosage	NDA	Patent No.	Patent Expiration
AEROSOL, METERED;INHALATION	021254	4,992,474	Aug 12, 2008
AEROSOL, METERED;INHALATION	021254	5,126,375	Aug 12, 2008
AEROSOL, METERED;INHALATION	021254	5,225,445	Aug 12, 2008
AEROSOL, METERED;INHALATION	021254	5,270,305	Sep 7, 2010
AEROSOL, METERED;INHALATION	021254	5,658,549	Feb 19, 2015
AEROSOL, METERED;INHALATION	021254	5,674,472	Apr 7, 2015



The contents of expired patents are public domain and free to use

# Track litigation to anticipate early generic launch, or to craft a better challenge

## US District Court Litigation for ADVAIR HFA

Patent	Case Name	Docket	Date Filed	Date Terminated	Cause	Court
7,500,444	Glaxo Group Ltd. v. Teva Pharmaceuticals USA, Inc.	1:17-cv-00357	2017-03-31	2017-06-21	35:0145	District Court, D. Delaware
7,832,351	Glaxo Group Ltd. v. Teva Pharmaceuticals USA, Inc.	1:17-cv-00357	2017-03-31	2017-06-21	35:0145	District Court, D. Delaware


Which patents are vital to generic launch?

What tactics have generics used to challenge patents?

# What's coming next?

## Clinical Trial Progress for ADVAIR HFA

Trial ID	Title	Status	Sponsor	Phase	Summary
NCT00102882	Study Of Asthma And Genetics In Patients To Be Treated With Fluticasone Propionate/Salmeterol Or Salmeterol Xinafoate	Completed	GlaxoSmithKline	Phase 4	This study may last up to 36-38 weeks. Patients will visit the clinic 11 times. A blood sample will be taken at Visit 1 to look at subjects' genes. Breathing tests will be done during the



Track manufacturing changes, new therapeutic indications, and more...

# European Protections

## Supplementary Protection Certificates

Supplementary Protection Certificate	SPC Country	SPC Expiration	SPC Description
C0014	France	2023-01-11	PRODUCT NAME: FLUTICASONE FUROATE; REGISTRATION NO/DATE: EU/1/07/434/001 20080111
C0067	France	2028-02-15	PRODUCT NAME: AZELASTINE OU SES SELS PHARMACEUTIQUEMENT ACCEPTABLES ET UN ESTER PHARMACEUTIQUEMENT ACCEPTABLE DE FLUTICASONE· NAT



Special EU protections


# Drug Prices

## Average Pharmacy Cost for ADVAIR HFA

Drug Name	NDC	Price/Unit (\$)	Unit	Date
ADVAIR HFA 115-21 MCG INHALER	00173-0716-20	25.45128	GM	2024-01-01
ADVAIR HFA 230-21 MCG INHALER	00173-0717-20	35.15312	GM	2024-01-01
ADVAIR HFA 45-21 MCG INHALER	00173-0715-20	20.03025	GM	2024-01-01
ADVAIR HFA 115-21 MCG INHALER	00173-0716-20	32.38076	GM	2023-06-21

## Best Wholesale Price for ADVAIR HFA

Drug Name	NDC	Count	Price (\$)	Price/Unit (\$)	Unit	Price Type
ADVAIR HFA 230MCG/21MCG INHL AEROSOL	00173-0717-22	8GM	224.96	28.12000	GM	Big4
ADVAIR HFA 45MCG/21MCG INHL AEROSOL	00173-0715-20	12GM	237.95	19.82917	GM	FSS
ADVAIR HFA 115MCG/21MCG INHL AEROSOL	00173-0716-20	12GM	395.64	32.97000	GM	FSS



Average cost and best price  
provide a range for launch pricing



# Annual sales revenues and units sold

Annual Sales Revenues and Units Sold for ADVAIR HFA

Drug Name	Revenues (USD)	Units	Year
ADVAIR HFA	\$1,178,727,000	2,099,000	2019
ADVAIR HFA	\$2,133,436,000	2,770,000	2018
ADVAIR HFA	\$1,255,556,000	3,148,000	2017
ADVAIR HFA	\$1,625,052,000	3,236,000	2016

Gauge market size and anticipate generic entry impact

# Finished product suppliers

## Finished Product Suppliers for ADVAIR HFA

Dosage	NDA	Supplier	NDC	Package
AEROSOL, METERED;INHALATION	021254	GlaxoSmithKline LLC	0173-0715-20	1 INHALER in 1 CARTON (0173-0715-20) / 120 AEROSOL, METERED in 1 INHALER
AEROSOL, METERED;INHALATION	021254	GlaxoSmithKline LLC	0173-0717-22	1 INHALER in 1 CARTON (0173-0717-22) / 60 AEROSOL, METERED in 1 INHALER
AEROSOL, METERED;INHALATION	021254	A-S Medication Solutions	50090-4504-0	1 INHALER in 1 CARTON (50090-4504-0) / 120 AEROSOL, METERED in 1 INHALER
AEROSOL, METERED;INHALATION	021254	Prasco Laboratories	66993-086-96	1 INHALER in 1 CARTON (66993-086-96) / 120 AEROSOL, METERED in 1 INHALER



Identify sources

# API suppliers

## Bulk API Sources for ADVAIR HFA

Vendor	Vendor Homepage	Vendor Sku	API Url
Smolecule	<a href="https://www.smolecule.com/">https://www.smolecule.com/</a>	S543013	<a href="https://www.smolecule.com/products/s543013">https://www.smolecule.com/products/s543013</a>
DC Chemicals	<a href="https://www.dcchemicals.com">https://www.dcchemicals.com</a>	DC34223	<a href="http://www.dcchemicals.com/product_show-Seretide.html">http://www.dcchemicals.com/product_show-Seretide.html</a>
TargetMol	<a href="https://www.targetmol.com/contact-us">https://www.targetmol.com/contact-us</a>	TP2406	<a href="https://www.targetmol.com/compound/Seretide">https://www.targetmol.com/compound/Seretide</a>
BenchChem	<a href="https://www.benchchem.com/">https://www.benchchem.com/</a>	B610793	<a href="https://www.benchchem.com/product/b610793">https://www.benchchem.com/product/b610793</a>

Identify raw ingredient sources

# Make Better Decisions

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