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Benzocaine

Trade Name:

Orajel teething products

Manufacturer/Distributor:

Church & Dwight

Status:

discontinued

Date Marketed in Canada (yyyy/mm/dd):

2018/05/23

Presentation:

Liquid: regular strength 7.5%. NPN:02229697

Gel: regular strength 7.5%. NPN: 00075876

Gel: extra strength for nighttime 10%. NPN: 02256401

Comments:

Based on the May 23, 2018 communication from the U.S. Food and Drug Administration (FDA) regarding over-the-counter (OTC) teething products containing benzocaine, the company is proactively discontinuing the distribution and sale of Orajel? teething products containing benzocaine. Orajel? teething products containing benzocaine and labeling have complied with applicable Health Canada and FDA requirements since the company acquired the brand in 2008. The discontinuation is effective immediately and includes Orajel? Regular Strength Gel for Teething (9.5G) and Orajel? Extra Strength Gel for Nighttime (9.5G).

Further Information:

Health Canada safety information: <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/13671a-eng.php> FDA Communication:

<https://www.fda.gov/Drugs/DrugSafety/ucm608265.htm>

Keywords: benzocaine
patient safety
methemoglobinemia

Access:

public

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Status:

<Any> ?

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<u>Generic Name</u>	<u>Common Trade Name(s)</u>	<u>Classification</u>	<u>Date Marketed in Canada (yyyy/mm/dd)</u>
<u>Abatacept</u>	Orencia	Co-stimulation modulator for rheumatoid arthritis	2006/09
<u>Abiraterone</u>	Zytiga	Androgen biosynthesis inhibitor	2011/08/08
<u>Acamprosate</u>	Campral	Alcohol abstinence aid	2007/03
<u>Acclidinium + formoterol</u>	Duaklir Genuair	Bronchodilator combination - LAMA plus LABA	2015/07/09
<u>Acclidinium bromide</u>	Tudorza Genuair	Bronchodilator	2013-09
<u>Adapalene + benzoyl peroxide</u>	Tactuo	Acne therapy	2011/04
<u>Adefovir dipivoxil</u>	Hepsera	Antiviral agent	2006/10
<u>Afatinib</u>	Giotrif	Protein kinase inhibitor	2014/05/28
<u>Albiglutide</u>	Eperzan	Antihyperglycemic agent	2016/02/19
<u>Alendronate</u>	Fosamax	Bone resorption inhibitor	2011/03
<u>Alglucosidase alfa</u>	Myozyme	Enzyme replacement therapy	2007/04
<u>Aliskiren and hydrochlorothiazide</u>	Rasilez HCT	Renin inhibitor and diuretic	2009/09
<u>Alitretinoin</u>	Toctino	Immunomodulator, antiinflammatory agent	2010/10/19
<u>Alogliptin</u>	Nesina	Oral antihyperglycemic agent	2014/10/08
<u>Alogliptin + metformin</u>	Kazano	Oral antihyperglycemic agent	2014/10/08
<u>Aluminum chloride hexahydrate</u>	Hydrosal gel	Antiperspirant	
<u>Aminophylline</u>	Phyllocontin	Bronchodilator	2010
<u>Apixaban</u>	Eliquis	Anticoagulant	2012/03

<u>Generic Name</u>	<u>Common Trade Name(s)</u>	<u>Classification</u>	<u>Date Marketed in Canada (yyyy/mm/dd)</u>
<u>Apomorphine</u>	Movapo	Nonergot-derivative dopamine receptor agonist	2018/04/xx
<u>Apremilast</u>	Otezla	Immunosuppressant agent	2014/12/08
<u>Aripiprazole</u>	Abilify	Antipsychotic agent	2009/07/03
<u>ASA + Meprobamate + Codeine + Caffeine</u>	282 MEP	Narcotic analgesic	
<u>Asenapine</u>	Saphris	Atypical antipsychotic	2012/03/16
<u>Asunaprevir</u>	Sunvepra	Antiviral agent	2016/04/22
<u>Avelumab</u>	Bavencio	Antineoplastic agent	2017/12/18
<u>Axitinib</u>	Inlyta	Anti-tumor agent	2012/09
<u>Azacitidine</u>	Vidaza	Antineoplastic agent	2009/12/07
<u>Azelastine + fluticasone</u>	Dymista	Antihistamine and corticosteroid agent	2015/10/22
<u>Azilsartan</u>	Edarbi	Antihypertensive agent	2013/03/27
<u>Azilsartan + chlorthalidone</u>	Edarbyclor	Antihypertensive agent	2013/03/27
<u>Azithromycin dihydrate</u>	Zmax SR	Antibiotic	2010/10/29
<u>Aztreonam</u>	Cayston	Antibacterial	2009/11/11
<u>Baricitinib</u>	Olumiant	Immunosuppressant	2018/08/17
<u>Belimumab</u>	Benlysta	Immunosuppressant	2011/10/01
<u>Bendamustine</u>	Treanda	Antineoplastic agent	2012/09/12
<u>Benralizumab</u>	Fasenra	Respiratory agent	2018/03/28

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