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OTC Decisions August-October: More Providers Enter Diclofenac, Lansoprazole, Loratadine Markets

by [Malcolm Spicer](#)

CDER's August-September OTC application approvals are highlighted by Arbor Pharmaceuticals' ivermectin 0.5% lice treatment. Orange Book changes also include four firms' approvals for labeling to market generic equivalents of Voltaren Arthritis Relief launched as an OTC switch since earlier in 2020.

Editor's note: HBW Insight's ongoing feature provides information on decisions during August-October by the US Food and Drug Administration on new drug applications, including ANDAs, for nonprescription drugs and on supplemental NDAs about label and package changes for approved OTC products.

The past three months offered relatively little in the way of additional OTC drug products approved for sales in the US until the final week of the period with Arbor Pharmaceuticals LLC receiving approval to introduce ivermectin 0.5% as a nonprescription lice treatment.

In other OTC application decisions by the Food and Drug Administration's Center for Drug Evaluation and Research from August through October, Tenshi Kaizen Private Ltd. received approval for the first generic equivalent of the Claritin Reditab loratadine 5-mg orally disintegrating tablets while Rubicon Research Pvt. Ltd. became the sixth firm with approval for a copy of the 10-mg Clarin Reditab formulation.

Yichang Humanwell Pharmaceutical Co. Ltd., meanwhile, is the latest manufacturer with approval to provide 200-mg ibuprofen oral analgesic in the US.

HBW INSIGHT

CITELINE COMMERCIAL

NDC 24338-185-04 **NEW!**



**Ivermectin Lotion 0.5%
Lice Treatment**

**Original Prescription
Strength**

**Now available without
a prescription!**

**One tube, one time,
10 minutes!**

SKLICE KILLS LICE

**No nit combing required
No second application
required**

**Includes:
1 Tube
Net Wt. 4 oz (117 g)**

Drug Facts

Active Ingredient Purpose
Ivermectin 0.5% Lice treatment

Use treats head lice

Warnings
For external use only. Use only on the scalp.

Do not use

- on children under 6 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

Ask a doctor before use if you

- have any skin conditions or sensitivities
- are pregnant or plan to become pregnant. It is not known if product can harm your unborn baby.
- are currently or planning to breastfeed. Avoid getting product on your breast to help prevent contact by your baby.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into eyes, gently flush with water
- eye redness, soreness, or irritation can occur
- dandruff, dry skin, or burning sensation of the skin can occur

Stop use and ask a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs
- rash develops

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Distributed by:
Arbor
Pharmaceuticals, LLC
Atlanta, GA 30328

Manufactured by:
DPT Laboratories, Ltd,
San Antonio, TX 78215



N 3 24338 18504 9

Drug Facts (continued)

Directions
Important: Read warnings before use

- children 6 months of age to under 12 years of age: an adult should supervise use
- adults and children 6 months of age and over:

Inspect

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and/or nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- examine small sections of the hair (1-2 inches wide) at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) are found, treat with product

Treat

- your hair and scalp must be **DRY** before applying product
- use the top of cap to break the tamper seal on the tube
- apply product directly to dry hair and scalp
- completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair
- use only amount to completely cover hair and scalp; up to 1 entire tube, and discard the remaining
- rub product throughout your hair
- it is important to completely cover your entire head so that all lice and eggs are exposed to the lotion. Be sure that each hair is coated from the scalp to the tip.

Wait and rinse

- allow product to stay on your hair and scalp for 10 minutes after it has been applied. Use a timer or clock. Start timing after you have completely covered your hair and scalp with product.
- after 10 minutes, rinse product completely from your hair and scalp using only water
- after rinsing, dry and style as usual. Wait 24 hours before applying shampoo.

After treatment

- wash your hands after applying product
- nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits
- this is a single use product. Discard tube after use.
- do not use again on the same person and same lice infestation without talking to a healthcare provider first
- if infestation continues, see a doctor for other treatments
- machine wash any bedding and clothing used by anyone having lice. Machine wash at high temperatures (150°F) and tumble in a hot dryer for 20 minutes.

Drug Facts (continued)

- after finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice.

Other information

- store at room temperature 68°-77°F. Excursions permitted to 59°-86°F.
- do not freeze
- keep carton and see Consumer Information Leaflet and warnings before use

Inactive ingredients
acetylated lanolin alcohol, cetyl acetate, citric acid, cyclomethicone, lanolin alcohol, methylparaben, oleyl alcohol, olive oil, polysorbate 80, propylparaben, shea butter, sodium citrate, sorbitan trioleate, and water

Questions?
1-888-516-4950
Monday – Friday: 9 am – 5 pm EST



**Ivermectin Lotion 0.5%
Lice Treatment**

**Original Prescription
Strength**

**Now available without
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**Includes:
1 Tube
Net Wt. 4 oz (117 g)**

**For single use.
Discard the tube
after use.**

U.S. Patent No. 6,103,248
and other patents pending.

ARBOR PHARMACEUTICALS HAS AN APPROVED LABEL FOR NONPRESCRIPTION SKLICE, ABOVE, BUT THE OTC SWITCH APPROVED IN OCTOBER IS NOT AVAILABLE FOR SALE YET.

CDER's Orange Book updates of the three months also include four firms' approvals for label additions for their generic equivalents of Voltaren Arthritis Relief (diclofenac 0.1 gel), which GlaxoSmithKline PLC launched as an OTC switch since earlier in 2020.

Sklice Makes Five

Arbor Pharmaceuticals received [CDER's approval](#) on 29 October for Sklice gel in a full OTC switch of ivermectin 0.5% for the topical treatment of head lice infestations in patients six months of age and older. The Atlanta-based firm had marketed the formulation Rx under the brand since

2012 and will continue using the brand for an OTC single-use lotion. (Also see "[In Latest US OTC Switch, Ivermectin 0.5% Lice Treatment Becomes Fully Nonprescription](#)" - HBW Insight, 27 Oct, 2020.)

With Arbor Pharmaceuticals' product the only Rx ivermectin 0.5% that has been approved for lice treatment available in the US, the same formulation no longer will be available by prescription, though higher concentrations of the ingredient, including formulations for pets, will remain Rx only.

The firm touts Sklice as the No. 1 prescribed "brand for head lice" based on its own data. Atlanta-based Arbor Pharmaceuticals' product is the fifth OTC switch CDER has approved in 2020, starting in February with Voltaren Arthritis Pain and 0.2% once-daily and 0.1% twice-daily formulations of olopatadine drops Alcon Laboratories Inc. markets under the Pataday brand. (Also see "[US OTC Switch Drought Ends: FDA Approves GSK Arthritis Gel, Alcon Allergy Eye Drops](#)" - HBW Insight, 17 Feb, 2020.)

Olopatadine became a full switch in July with the FDA's approval of Alcon's sNDA for an OTC product indicated for ocular allergies, or allergic conjunctivitis, with 0.7% concentration of the ingredient and marketed as Once Daily Relief Extra Strength. (Also see "[With Pataday Extra Strength, Alcon Eyes Consumers Looking For OTC 24-Hour Eye Allergy Remedy](#)" - HBW Insight, 13 Jul, 2020.)

ORIGINAL PRESCRIPTION STRENGTH

Walgreens

Diclofenac Gel

DICLOFENAC SODIUM TOPICAL GEL, 1% (NSAID) - ARTHRITIS PAIN RELIEVER

ANTI-INFLAMMATORY

• For daily treatment of arthritis pain

Compare to the active ingredient in Voltaren Arthritis Pain Gel[†]

NDC 0383-7065-10

NEW

FOR EXTERNAL USE ONLY

NET WT 3.53 OZ (100 g)

Medicated Gel Clinically Proven to Relieve Arthritis Pain

TREATMENT AREAS

Hand Wrist Elbow Foot Ankle Knee

Not for use on any other body area (such as back, hip or shoulder)

[†]Walgreens Pharmacist Survey

[‡]This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, PLC, distributor of Voltaren Arthritis Pain Gel.

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200 WILMOT RD., DEERFIELD, IL 60015

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Code: GO/DRUGS/361

DOB3B/00

WALGREENS DICLOFENAC 0.1% GEL IS ONE OF SEVERAL PRIVATE LABEL OR STORE BRAND PRODUCTS MADE BY ENCUBE ETHICALS WHICH BECAME AVAILABLE IN THE US AFTER ITS ANDA FOR LABEL AND INSERT CHANGES WAS APPROVED IN AUGUST.

Pataday also was on CDER's radar on September. It approved Alcon Labs' sNDA changes to labeling, containers and cartons for the 0.2% and 0.1% formulations; the approval letters and images of the changes were not included in the Orange Book entry.

More Claritin Reditab Generics

Rubicon Research on 10 September received CDER's approval of its ANDA for 10-mg loratadine in an orally disintegrating formulation like Bayer AG's Claritin Reditab product, which also is marketed as a hives treatment. Mumbai, India-based Rubicon is the sixth firm with approval to provide in the US an ingredient recognized as a generic equivalent of Claritin Reditab.

Tenshi Kaizen, of Bengaluru, India, on 18 September received approval to provide 5-mg orally disintegrating loratadine in the US. The approval is the first generic competition for Bayer's 5-mg Claritin Reditab formulation.

Bayer, meanwhile, received approval on 7 August for an sNDA on labeling for an 80-count package of cool mint flavor Children's Claritin in chewable 5- and 10-mg loratadine formulations.

Chinese firm Yichang Humanwell Pharmaceutical is the 17th manufacturer to receive CDER's approval to provide in the US 200-mg ibuprofen that follow on the Advil brand marketed by GlaxoSmithKline plc. The center approved the firm's ANDA on 19 October.

Sofgen Pharmaceuticals LLC, of Dania Beach, FL, on 6 August received approval for an sNDA for changes to labeling, containers and cartons for its 200-mg ibuprofen formulated as a free acid and potassium salt as GSK uses in Advil Liqui-Gels.

Rx Diclofenac Gels Move To OTC

GSK, like other drug firms, was marketing diclofenac 0.1% gel external analgesic in Rx drugs before it received the FDA's approval to market the formulation OTC Voltaren Arthritis Relief. The FDA approval for the UK pharma's switch didn't come with three-year marketing exclusivity because a clinical trial wasn't required in the sNDA. (Also see "[US OTC Switch Drought Ends: FDA Approves GSK Arthritis Gel, Alcon Allergy Eye Drops](#)" - HBW Insight, 17 Feb, 2020.)

Perrigo Co. plc, received approval for its ANDA for an OTC diclofenac 0.1% gel in April, before GSK launched sales of Voltaren Arthritis Relief. (Also see "[Perrigo Has Approval For Copy Of OTC Voltaren Arthritis Relief Before GSK Launches The Brand](#)" - HBW Insight, 6 Apr, 2020.)

CDER's OTC decisions over the past three months indicate three other firms have label or package inserts approved for their generic equivalents of Voltaren Arthritis Relief. However, unlike Perrigo, the other three firms don't have an entry for approval for OTC sales of their diclofenac 0.1% gels before they received CDER's approval of label or package inserts for nonprescription products.

Mylan N.V.'s OTC diclofenac 0.1% gel ANDA for labeling or inserts was approved on 6 August. Mylan, which is merging with Pfizer Inc.'s Upjohn business for mature Rx brand and off-patent products, had a prescription formulation approved in May 2019. (Also see "[Divided FTC Okays Mylan-Upjohn Merger But Election Outcome Could Impede Future Deals](#)" - Pink Sheet, 30 Oct, 2020.)

Indian firm Encube Ethicals Ltd.'s labeling and inserts ANDA for an OTC generic of Voltaren Arthritis Relief was approved on 11 August. The Indian firm's Rx of the product was approved in January, shortly before CDER approved GSK's OTC switch of the formulation.

Amneal Pharmaceuticals LLC's Rx diclofenac 0.1 gel was approved in 2016; the Bridgewater, NJ-based business of Swiss firm Amneal Pharmaceuticals Company GmbH received CDER's approval for its ANDA for labeling and inserts for a generic equivalent of Voltaren Arthritis Relief on 13 August.

Dublin-based Perrigo's ANDA for labeling and inserts ANDA for its diclofenac 0.1% gel was approved on 23 October. Prior to receiving CDER's approval for the OTC product in April, it acquired an Rx formulation that had been approved for Capstone Development Solutions in 2016.

More Lansoprazole PPI Providers

Perrigo also was one of three firms to receive CDER's approval during the three months for labeling and inserts for 15-mg lansoprazole in delayed-release tablets, generic equivalents of Prevacid 24HR, which Perrigo also markets after acquiring the proton pump inhibitor brand from GSK in September 2019. (Also see "[Perrigo Feeds OTC Brand Play With Prevacid As GSK Thins Consumer Lineup](#)" - HBW Insight, 5 Sep, 2019.)

The approval letter and images of the labeling and inserts for Perrigo's and the other firm's lansoprazole ANDAs were not included in the Orange Book entries. The labeling and inserts changes likely follow the [latest changes approved](#) for Prevacid 24HR labeling, in April 2019. An sNDA GSK submitted before selling the brand was approved to add to labels the statement, "Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs."

The other OTC lansoprazole 15-mg lansoprazole delayed-release tablet providers with approvals

for labeling and insert changes were Dr Reddy's Laboratories Ltd. on 7 October and Lannett Co. Inc. on 8 October.

Dr Reddy's also continued expanding its US nicotine replacement therapy footprint during the past three months. The Indian firm on 4 August became the fourth manufacturer approved to provide in the US generics of GSK's Nicorette (nicotine polacrilex) 2- and 4-mg lozenges.