

Tradename
(genericname)
90 mcg nasal spray

Treats seasonal and year-round nasal allergy symptoms in adults and children 4 years and older

Tradename

is a prescription nasal spray that can temporarily relieve itchy, runny nose, sneezing and itchy, watery eyes from both outdoor and indoor allergies. Starts working in just 1-2 weeks!

Important Risk Information

DO NOT take Tradename if you are allergic to genericname or any of the ingredients in Tradename

Immune System Problems. Tradename may cause immune system problems that may increase the risk of infection. Call your healthcare provider right away if you develop any signs of infections including: fever, feeling very tired or weak, nausea, vomiting, cough, or body aches.

Reduced adrenal function (adrenal insufficiency). Tradename may cause adrenal insufficiency, a condition where the adrenal glands do not make enough steroid hormone. Tell your healthcare provider if you have any of the following symptoms: tiredness, weakness, nausea, vomiting, or low blood pressure.

Eye problems. Tradename may cause cataracts or glaucoma (increased pressure in your eye). You should have regular eye exams while using Tradename.

Serious allergic reactions. Call your healthcare provider or get medical care if you get any of the following signs of a serious allergic reaction: rash, hives, swelling of your face, mouth, and tongue, breathing problems, or low blood pressure.

Before you use Tradename, tell your healthcare provider about all of your medical conditions, including if you have or have had: recent or unhealed nasal sores, nasal surgery, or nasal injury, eye or vision problems including cataracts or glaucoma (increased pressure in your eye), tuberculosis or any untreated fungal, bacterial, or viral infections, or eye infections. Also Tell your healthcare provider if you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed.

Common side effects of Tradename include: infection of the nose and throat, headache, viral infection, nosebleeds, and cough.

Tradename is:

- Non-drowsy

Please see Important Information about Tradename on the next page.

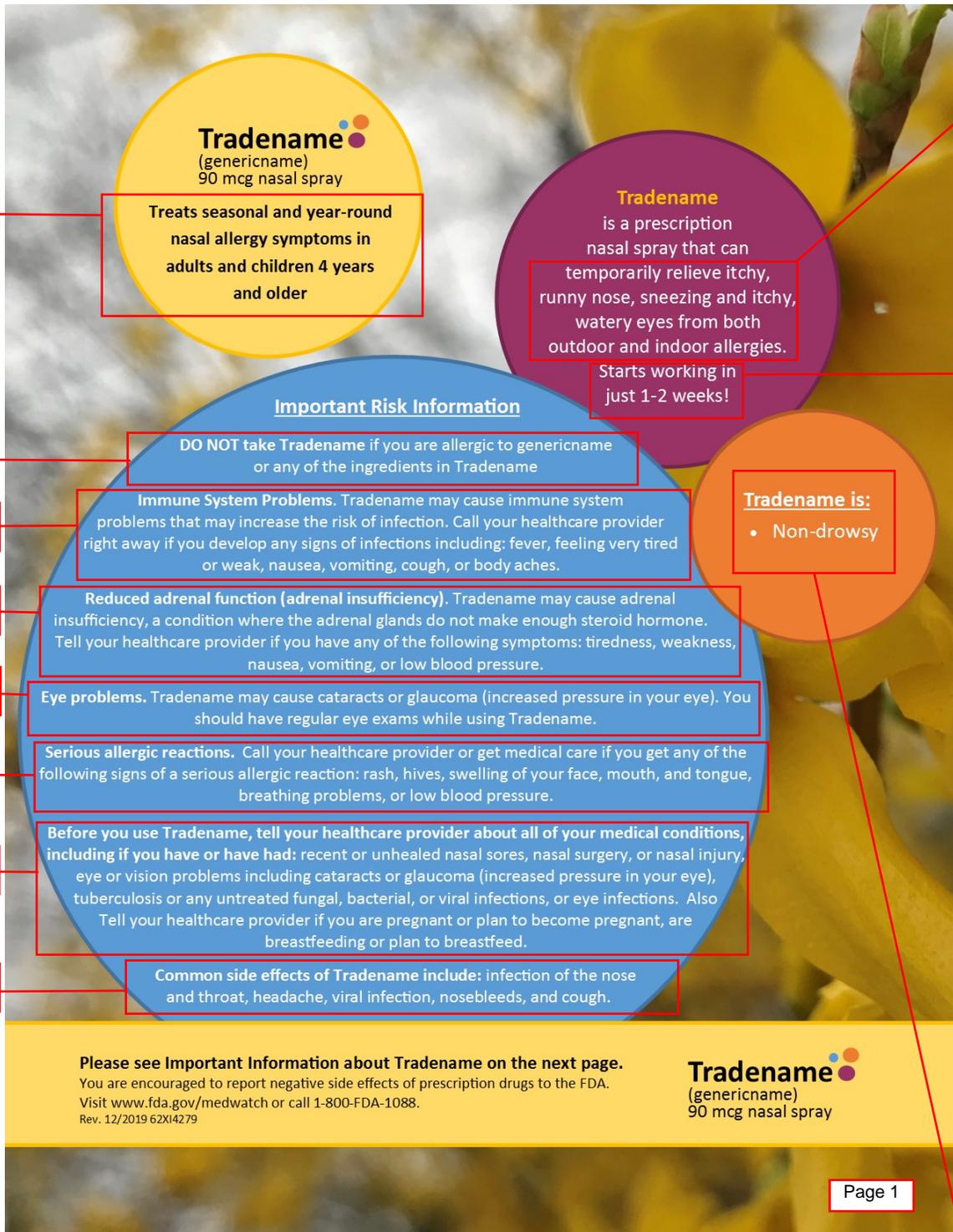
You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Rev. 12/2019 62X14279

Tradename
(genericname)
90 mcg nasal spray

Mock Print Ad (Annotated)



Ref 1:
Brown et al. 2008
(page 2, paragraph 2,
lines 2-7).

Annotated PI
(page 12, section 14,
paragraph 5, line 3)

Ref 1:
Brown et al. 2008
(page 6, paragraph 3,
lines 3-4).

CFL Analysis:
**Passes CFL 3-factor
test**

Factor 1:
Compared to the
FDA-required labeling:
-Does not relate to a
different indication
-Does not relate to a
patient population
outside of the
approved population
-No conflict with any
use limitations or
directions for
handling, preparing
or using the product
-No conflict with the
recommended
dosage or use
regimen, route of
administration, or
strength

Factor 2:
-Does not increase
the potential for harm
to health relative to
the information in the
FDA-required
labeling

Factor 3:
-Does not conflict with
directions in the
FDA-required
labeling to enable
the product to be
safely and effectively
used under the
conditions
represented/
suggested

PPI Annotated to Print
Ad (page 1, B)

PPI Annotated to Print
Ad (page 1, C)

PPI Annotated to Print
Ad (page 1, A)

PPI Annotated to Print
Ad (page 1, E)

PPI Annotated to Print
Ad (page 1, F)

PPI Annotated to Print
Ad (page 1, G)

PPI Annotated to Print
Ad (page 1, D)

PPI Annotated to Print
Ad (page 1, H)

Tradename
(genericname)
90 mcg nasal spray

Treats seasonal and year-round
nasal allergy symptoms in
adults and children 4 years
and older

Tradename
is a prescription
nasal spray that can
temporarily relieve itchy,
runny nose, sneezing and itchy,
watery eyes from both
outdoor and indoor allergies.

Starts working in
just 1-2 weeks!

Important Risk Information
**DO NOT take Tradename if you are allergic to genericname
or any of the ingredients in Tradename**

Immune System Problems. Tradename may cause immune system
problems that may increase the risk of infection. Call your healthcare provider
right away if you develop any signs of infections including: fever, feeling very tired
or weak, nausea, vomiting, cough, or body aches.

Reduced adrenal function (adrenal insufficiency). Tradename may cause adrenal
insufficiency, a condition where the adrenal glands do not make enough steroid hormone.
Tell your healthcare provider if you have any of the following symptoms: tiredness, weakness,
nausea, vomiting, or low blood pressure.

Eye problems. Tradename may cause cataracts or glaucoma (increased pressure in your eye). You
should have regular eye exams while using Tradename.

Serious allergic reactions. Call your healthcare provider or get medical care if you get any of the
following signs of a serious allergic reaction: rash, hives, swelling of your face, mouth, and tongue,
breathing problems, or low blood pressure.

**Before you use Tradename, tell your healthcare provider about all of your medical conditions,
including if you have or have had: recent or unhealed nasal sores, nasal surgery, or nasal injury,
eye or vision problems including cataracts or glaucoma (increased pressure in your eye),
tuberculosis or any untreated fungal, bacterial, or viral infections, or eye infections. Also
Tell your healthcare provider if you are pregnant or plan to become pregnant, are
breastfeeding or plan to breastfeed.**

**Common side effects of Tradename include: infection of the nose
and throat, headache, viral infection, nosebleeds, and cough.**

Tradename is:
• Non-drowsy

Please see Important Information about Tradename on the next page.
You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
Rev. 12/2019 62X14279

Tradename
(genericname)
90 mcg nasal spray

Ref 2:
Lee et al. 2010
(pg 15, ¶ 3, lines 1-6).

CFL Analysis:

Passes CFL 3-factor test

Factor 1:
Compared to the FDA-required labeling:
-Does not relate to a different indication
-Does not relate to a patient population outside of the approved population
-No conflict with any use limitations or directions for handling, preparing or using the product
-No conflict with the recommended dosage or use regimen, route of administration, or strength

Factor 2:
-Does not increase the potential for harm to health relative to the information in the FDA-required labeling

Factor 3:
-Does not conflict with directions in the FDA-required labeling to enable the product to be safely and effectively used under the conditions represented/suggested

Patient Information
TRADENAME
(genericname)
nasal spray

Read this Patient Information that comes with TRADENAME before you start using it and each time you get a refill. There may be new information. This Patient Information does not take the place of talking to your healthcare provider about your medical condition or treatment.

A

What is the most important information I should know about TRADENAME?

TRADENAME may cause serious side effects, including:

- **immune system problems** that may increase the risk of infection. Call your healthcare provider right away if you develop any signs of infections including:
 - fever
 - feeling very tired or weak
 - nausea
 - vomiting
 - cough
 - body aches

B

What is TRADENAME?

- TRADENAME is a prescription medicine used to treat seasonal and year-round nasal allergy symptoms (allergic rhinitis) in adults and children 4 years and older.
- It is not known if TRADENAME is safe or effective in children under 4 years of age.

C

Do not take TRADENAME if you are allergic to genericname or any of the ingredients in TRADENAME. See the end of this Patient Information leaflet for a complete list of ingredients in TRADENAME.

D

Before you use TRADENAME, tell your healthcare provider about all of your medical conditions, including if you:

- have recent or unhealed nasal sores, nasal surgery, or nasal injury.
- have or have had eye or vision problems including cataracts or glaucoma (increased pressure in your eye).
- have or have had tuberculosis or any untreated fungal, bacterial, or viral infections, or eye infections.
- are pregnant or plan to become pregnant. It is not known if TRADENAME will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TRADENAME passes into your breast milk. You and your healthcare provider should decide if you will use TRADENAME if you plan to breastfeed.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take TRADENAME?

- Read the Instructions for Use at the end of this leaflet for more information about the right way to use TRADENAME.
- Use TRADENAME exactly as your healthcare provider tells you to use it.
- Spray TRADENAME nasal spray into your nose only. **Do not** spray it into your eyes or mouth.
- **Do not** use more than your healthcare provider tells you.
- Throw away your TRADENAME bottle after using 120 sprays. Even though the bottle may not be completely empty, you may not get the correct dose of medicine.

What are the possible side effects of TRADENAME?

TRADENAME may cause serious side effects including:

See “What is the most important information I should know about TRADENAME?”

E

- **Reduced adrenal function (adrenal insufficiency).** TRADENAME may cause adrenal insufficiency, a condition where the adrenal glands do not make enough steroid hormone. Tell your healthcare provider if you have any symptoms of adrenal insufficiency including:
 - tiredness
 - weakness
 - nausea
 - vomiting
 - low blood pressure

F

- **Eye problems.** TRADENAME may cause cataracts or glaucoma (increased pressure in your eye). You should have regular eye exams while using TRADENAME.

G

- **Serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following signs of a serious allergic reaction:
 - rash
 - hives
 - swelling of your face, mouth, and tongue
 - breathing problems
 - low blood pressure

- **Common side effects of TRADENAME include:**
 - infection of the nose and throat
 - nosebleeds
 - headache
 - cough
 - viral infection

These are not all the possible side effects of TRADENAME. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TRADENAME?

- Store TRADENAME in the original container.
- Store TRADENAME at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep TRADENAME and all medicines out of the reach of children.

General Information about the safe and effective use of TRADENAME

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. Do not use TRADENAME for a condition for which it was not prescribed. Do not give TRADENAME to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TRADENAME that is written for healthcare professionals.

What are the ingredients in TRADENAME?

Active ingredient: genericname

Inactive ingredients: benzalkonium chloride, dextrose, microcrystalline cellulose, phenylethyl alcohol, carboxymethylcellulose sodium, polysorbate 80, purified water

Distributed by: Smith Pharmaceuticals

Important Notes:

- The annotated mock ad is provided for informational purposes related to the methods for annotating submissions only. This ad does not necessarily represent all of the risk or efficacy information that should be included in promotional materials in general.
- This presentation is not meant to imply that these are the only methods that may be used to annotate submissions.
- Different examples of methods for annotating have been included in the mock ad to show various ways a submission could be annotated. However, we recommend using a consistent method throughout your submission for all references included in the submission.
- This example includes one example of a reference cited in the mock ad (i.e., the annotated PPI) that is highlighted/annotated to the mock ad; it does not include examples of all the references listed in the mock ad annotations. However, all references cited in the annotations, should be included with advisory submissions.
- A page number was added to the annotated version of the mock ad to improve efficiency of the review and communication of OPDP's advisory comments.
- The CFL-analyses included in the annotated mock ad are examples of how optional CFL-analyses could be included to help facilitate OPDP's review of information not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.
 - As a reminder, per the guidance titled, "Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers Guidance for Industry," to be truthful and non-misleading, representations or suggestions made by firms about their products need to be grounded in fact and science and presented with appropriate context. Any data, studies, or analyses relied on should be scientifically appropriate and statistically sound to support the representations or suggestions made in a CFL promotional communication.

Mock eCTD Advisory Submission Example with Helpful Tip

1.15 Promotional material (Consumer)

1.15.1 Correspondence relating to promotional materials

1.15.1.1 Request for advisory comments on launch materials

Request for consumer launch advisory for brochure and print ad 20200501

1.15.2 Materials (Request for Advisory Launch)

1.15.2.1 Material (Brochure)(62XI9845)

1.15.2.1.1 Clean version

Brochure 62XI9845 20200501 CLEAN

1.15.2.1.2 Annotated version

Brochure 62XI9845 20200501 ANNOTATED

1.15.2.1.3 Annotated labeling version

TRADENAME PI Rev 11/2019

TRADENAME PPI Rev 11/2019 annotated to brochure

1.15.2.1.4 Annotated references

Reference 1: Smith et al. 2014 for brochure

1.15.2.1 Material (Print Ad)(62XI4279)

1.15.2.1.1 Clean version

Print ad 62XI4279 20200501 CLEAN

1.15.2.1.2 Annotated version

Print ad 62XI4279 20200501 ANNOTATED

1.15.2.1.3 Annotated labeling version

TRADENAME PI Rev 11/2019 <Hyperlinked in us-regional file to PI in Section 1.15.2.1.3 for brochure>

TRADENAME PPI Rev 11/2019 annotated to print ad

1.15.2.1.4 Annotated references

Reference 1: Brown et al. 2008 for print ad

Reference 2: Lee et al. 2010 for print ad

eCTD Helpful Tip:

- Reference links may be used if the annotated copies of either the label or reference(s) are identical across materials.
 - In the above example, the PI in section 1.15.2.1.3 for the print ad is identical to the PI in section 1.15.2.1.3 for the brochure. Therefore, a hyperlink to the PI in section 1.15.2.1.3 for the brochure was included in section 1.15.2.1.3 for the print ad.
 - In the above example, the annotated PPI in in section 1.15.2.1.3 for the print ad is NOT identical to the annotated PPI in section 1.15.2.1.3 for the brochure. Therefore, separate reference documents were included in section 1.15.2.1.3 for the brochure and section 1.15.2.1.3 for the print ad.