

PART III: CONSUMER INFORMATION

PrULTIBRO® BREEZHALER®
Indacaterol (as maleate)/glycopyrronium (as bromide)
inhalation powder hard capsules

Read this carefully before you start taking ULTIBRO® BREEZHALER® and each time you get a refill. This leaflet is a summary and will not tell you everything about ULTIBRO® BREEZHALER®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about ULTIBRO® BREEZHALER®.

ABOUT THIS MEDICATION

What the medication is used for:

ULTIBRO® BREEZHALER® is used long term once daily to treat breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

It is not for treating sudden, severe symptoms of COPD.

What it does:

ULTIBRO® BREEZHALER® contains two active substances called indacaterol and glycopyrronium.

- Indacaterol is a long-acting beta₂ agonist (LABA)
- Glycopyrronium is a long-acting muscarinic antagonist (LAMA)

Both active ingredients belong to a group of medicines called bronchodilators. They help to open and relax the muscles of the airways. This allows more air to get in and out of the lungs and helps prevent shortness of breath and wheezing.

This medicine does not cure COPD but helps to control it. It is therefore important that you take ULTIBRO® BREEZHALER® regularly even if you feel fine.

When it should not be used:

Do not use ULTIBRO® BREEZHALER®:

- **If you have a severe allergy to indacaterol maleate or glycopyrronium bromide or any other component of ULTIBRO® BREEZHALER®. Ask your doctor, nurse or pharmacist if you are not sure.**
- **To treat sudden, severe symptoms of COPD such as sudden shortness of breath or wheezing.**
- **To treat asthma.**
- **ULTIBRO® BREEZHALER® should not be used in children. COPD does not occur in children.**
- **If you have a lactose or severe milk protein allergy.**
- **If you are younger than 18 years of age.**

What the medicinal ingredient is:

Indacaterol maleate and glycopyrronium bromide

What the non-medicinal ingredients are:

Carrageenan, FD&C Yellow 5/Tartrazine, hypromellose, lactose monohydrate (which contains milk proteins), magnesium stearate, potassium chloride, purified water.

What dosage forms it comes in:

Transparent yellow capsules for oral **inhalation**. Each capsule contains 110 mcg indacaterol and 50 mcg glycopyrronium.

Each pack includes an inhaler and capsules (in blister strips) that contain the medicine as inhalation powder.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ULTIBRO® BREEZHALER® should only be used to treat COPD.

ULTIBRO® BREEZHALER® should not be used to treat asthma.

You are advised that in patients with asthma, long-acting beta₂-agonist (LABA) medicines, may increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding with salmeterol is considered a class effect of LABA, including indacaterol maleate, one of the active ingredients of ULTIBRO® BREEZHALER®.

BEFORE you use ULTIBRO® BREEZHALER® talk to your doctor, nurse or pharmacist if you:

- Are pregnant or planning to become pregnant;
- Are a breast-feeding mother;
- Are an asthmatic (in this case you should not be treated with ULTIBRO® BREEZHALER®);
- Have heart problems, such as rapid or irregular heart beat or abnormal electrical signal called “prolongation of the QT interval”;
- Have high blood pressure;
- Have seizures or fits;
- Have thyroid gland problems or disease;
- Suffer from diabetes;
- Are taking similar medicines for your lung disease;
- Are taking any medications including eye drops, this includes medications you can buy without prescription;
- Have problems with your kidneys;
- Have severe liver problems;
- Have eye problems, such as glaucoma or eye pain, blurred vision, see halos around lights or coloured images;
- Have an enlarged prostate, problems passing urine, or painful urination;

- Have a severe allergy to milk proteins. Ask your doctor if you are not sure;
- Have had allergies to atropine or related medicines, for example ipratropium or tiotropium;
- Have allergies to food or drugs.

These capsules are intended for inhalation only.

DO NOT SWALLOW.

ULTIBRO® BREEZHALER® should not be used more frequently than once daily. Do not exceed the prescribed dose.

This medication has been prescribed for you and should not be given to other people.

Avoid getting the drug powder into your eyes. This may result in eye pain and/or discomfort, temporary blurring of vision, and/or coloured images in association with red eyes. These may be signs of acute narrow-angle glaucoma. Should any of these symptoms develop, consult a doctor immediately.

Remember to tell any other doctor, nurse, dentist or pharmacist you consult that you are taking this medication.

Driving and Using Machines:

The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery.

During the treatment with ULTIBRO® BREEZHALER®, tell your doctor immediately if you experience any of the following symptoms:

- **stop taking ULTIBRO® BREEZHALER® and tell your doctor immediately** if you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation of ULTIBRO® BREEZHALER® (signs of paradoxical bronchospasm).
- **stop taking ULTIBRO® BREEZHALER® and tell your doctor immediately** if you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, hives or itching, skin rash (signs of hypersensitivity reaction). Do not use ULTIBRO® BREEZHALER® again before speaking with your doctor.
- If your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment.
- **stop taking ULTIBRO® BREEZHALER® and tell your doctor immediately** if you experience eye pain or discomfort, temporary blurring of vision, visual halos or colored images in association with red eyes; these may be signs of an acute attack of narrow-angle glaucoma.

ULTIBRO® BREEZHALER® does not relieve sudden symptoms of COPD. Always have a short-acting bronchodilator medicine with you to treat acute symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.

Get emergency medical care if:

- breathing problems worsen quickly

- you use your short-acting bronchodilator medicine, but it does not relieve your breathing problems

Ask your doctor, nurse or pharmacist for advice before taking any additional medicine.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor, nurse or a pharmacist if you are taking or have recently taken any other medicines, including prescription and non-prescription drugs, eye drops, vitamins, and herbal supplements.

The following may interact with ULTIBRO® BREEZHALER®:

- Medicines used in the treatment of depression or sad mood (e.g. tricyclic antidepressants, monoamine oxidase inhibitors);
- Other medications (including combinations) that contain a long-acting beta agonist (LABA), such as formoterol, salmeterol, indacaterol, vilanterol, olodaterol;
- Other medications that contain a short-acting, or a long-acting muscarinic antagonist (LAMA) (e.g. ipratropium, tiotropium, glycopyrronium, aclidinium, umeclidinium).
- Ask your doctor or pharmacist if any of your other medicines are LABA or ipratropium or LAMA containing medicines;
- Medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water tablets” and used to treat high blood pressure, e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines used for breathing problems (e.g. theophylline) or steroids (e.g. prednisolone);
- Beta-blockers used in the treatment of high blood pressure or other heart problems (e.g. propranolol) or in the treatment of glaucoma (e.g. timolol);
- Ketoconazole (used to treat fungal infections);
- Ritonavir (Anti-HIV medicine);
- Erythromycin (used to treat bacterial infections);
- Verapamil (used to treat high blood pressure, severe chest pain, irregular heartbeat).

PROPER USE OF THIS MEDICATION

Always use this medicine exactly as your doctor, nurse or pharmacist has told you. Check with your doctor, nurse or pharmacist if you are not sure. Do not exceed the recommended dose prescribed by your doctor.

You can inhale ULTIBRO® BREEZHALER® before or after food or drink.

Usual adult dose:

Inhale the contents of one capsule through the mouth each day, every day at the same time. Inhaling ULTIBRO® BREEZHALER® at the same time each day will help to minimize

your symptoms throughout the day and night and will also help you to remember to use it.

You only need to inhale once a day to help you breathe easier because the effects of ULTIBRO® BREEZHALER® last for 24 hours.

Use ULTIBRO® BREEZHALER® even when you have no breathing problems or other symptoms of COPD.

How long to use ULTIBRO® BREEZHALER®

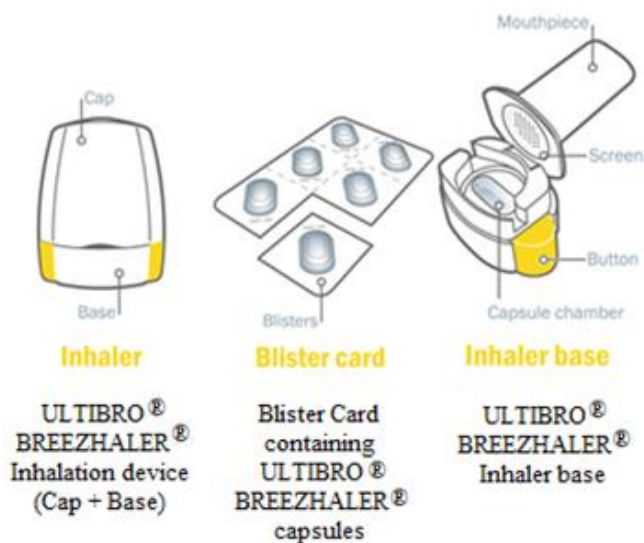
Keep using ULTIBRO® BREEZHALER® for as long as your doctor tells you.

COPD is a long-term disease and you should use ULTIBRO® BREEZHALER® every day and not only when you have breathing problems or other symptoms of COPD.

If you have questions about how long to continue your treatment with ULTIBRO® BREEZHALER®, talk to your doctor or your pharmacist.

Each ULTIBRO® BREEZHALER® pack contains

- One or more ULTIBRO® BREEZHALER® inhalers consisting of a cap and a base
- One or more blisters containing ULTIBRO® BREEZHALER® capsules to be used in the inhaler



Only use the ULTIBRO® BREEZHALER® inhaler contained in this pack to inhale the powder in a capsule.

Do not use ULTIBRO® BREEZHALER® capsules with any other inhaler. Do not use ULTIBRO® BREEZHALER® inhaler to take any other capsule medicine.

Capsules should always be stored in the blister strip and only removed immediately before use.

When you start a new pack, use the new ULTIBRO® BREEZHALER® inhaler supplied in this new pack. Dispose of each inhaler after 30 days of use. Ask your pharmacist how to dispose of medicines and inhalers no longer required.

Do not swallow ULTIBRO® BREEZHALER® capsules. The powder in the capsules is for you to inhale.

How to use your ULTIBRO® BREEZHALER® inhaler:

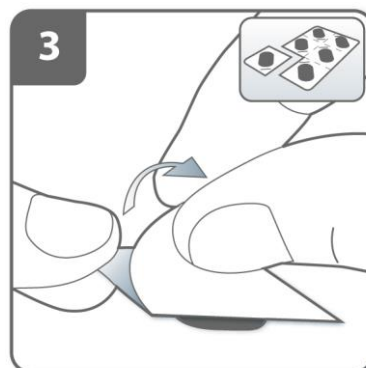


Pull off cap.



Open inhaler:

Hold the base of the inhaler firmly and tilt the mouthpiece to open the inhaler.

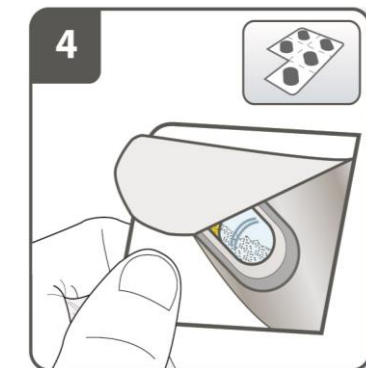


Prepare capsule:

Separate one of the blisters from the blister card by tearing along the perforation.

Take one blister and peel away the protective backing to expose the capsule.

Do not push capsule through foil.

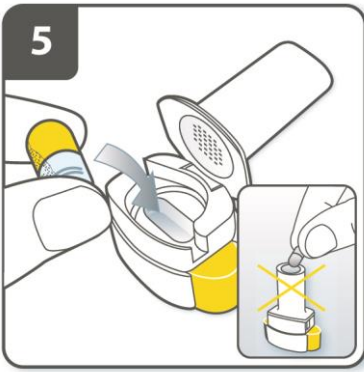


Remove one ULTIBRO® BREEZHALER® capsule:

Capsules should always be stored in the blister and only removed immediately before use.

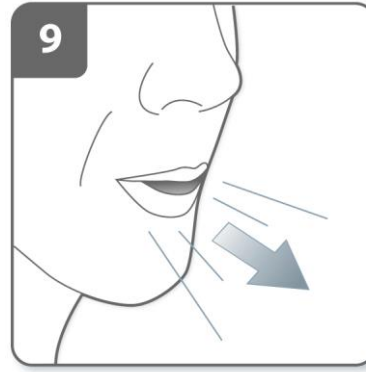
With dry hands, remove capsule from the blister.

Do not swallow the ULTIBRO® BREEZHALER® capsule.



Insert capsule:
Place the capsule into the capsule chamber.

Never place a capsule directly into the mouthpiece.

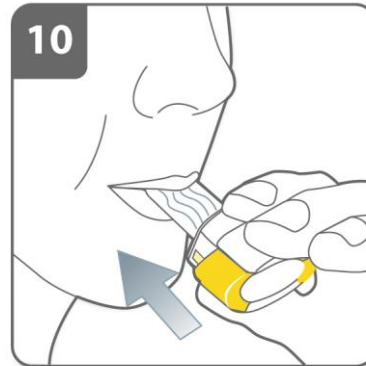


Breathe out:
Before placing the mouthpiece in your mouth, breathe out fully.

Never blow into the mouthpiece.

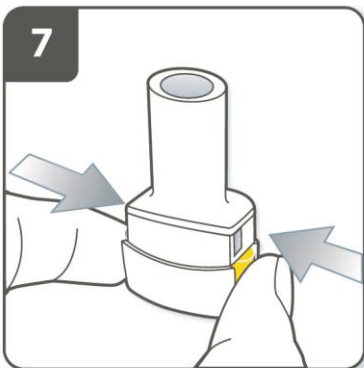


Close the inhaler:
Close the inhaler fully. You should hear a 'click' as it fully closes.



Inhale the medicine:
Before breathing in:

- Hold the inhaler as shown in the picture with the buttons to the left and right (not up and down).
- Place the mouthpiece in your mouth and close your lips firmly around the mouthpiece.
- Breathe in rapidly but steadily, as deeply as you can. **Do not press the piercing buttons.**



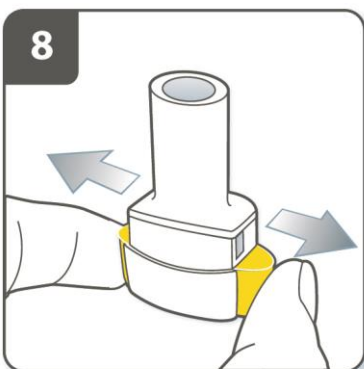
Pierce the capsule:
Hold the inhaler upright with the mouthpiece pointing up.

Press both buttons together firmly at the same time. You should hear a 'click' as the capsule is being pierced.



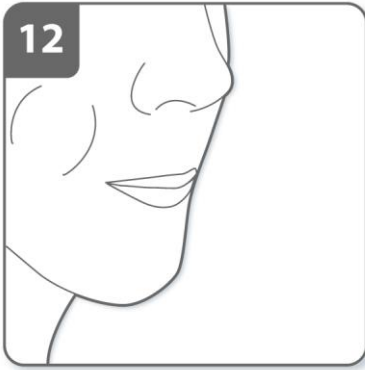
Note:
As you breathe in through the inhaler, the capsule spins around in the chamber and you should hear a whirring noise. You will experience a sweet taste as the medicine goes into your lungs.

Do not press the piercing buttons more than once.



Release the buttons fully.

If you do not hear a whirring noise, the capsule may be stuck in the capsule chamber. If this occurs, open the inhaler and carefully loosen the capsule by tapping the base of the inhaler. **Do not press the piercing buttons to loosen the capsule.** Repeat steps 9 and 10 if necessary.

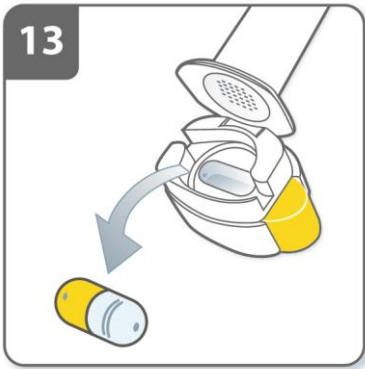


Hold breath:

Continue to hold your breath for at least 5-10 seconds or as long as comfortably possible while removing the inhaler from your mouth. Then breathe out.

Open the inhaler to see if any powder is left in the capsule. If there is powder left in the capsule, close the inhaler and repeat steps 9 to 12. Most people are able to empty the capsule with one or two inhalations.

Some people occasionally cough briefly soon after inhaling the medicine. If you do, don't worry, as long as the capsule is empty, you have received the full dose.



Remove capsule:

After you have finished taking your daily dose of ULTIBRO[®] BREEZHALER[®], open the mouthpiece again, remove the empty capsule by tipping it out of the capsule chamber, and discard it. Close the inhaler and replace the cap.

Do not store the capsules in the ULTIBRO[®] BREEZHALER[®] inhaler.

REMEMBER:

- **Do not swallow ULTIBRO[®] BREEZHALER[®] capsules.**
- **Only use the ULTIBRO[®] BREEZHALER[®] inhaler contained in this pack.**
- ULTIBRO[®] BREEZHALER[®] capsules must always be stored in the blister, and only removed immediately before use.
- Never place a ULTIBRO[®] BREEZHALER[®] capsule directly into the mouthpiece of the ULTIBRO[®] BREEZHALER[®] inhaler.
- Do not press the piercing buttons more than once.
- Never blow into the mouthpiece of the ULTIBRO[®] BREEZHALER[®] inhaler.
- Always release the push buttons before inhalation.
- Never wash the ULTIBRO[®] BREEZHALER[®] inhaler with water. Keep it dry. See below "How to clean your inhaler".

- Never take the ULTIBRO[®] BREEZHALER[®] inhaler apart.
- Always keep the ULTIBRO[®] BREEZHALER[®] inhaler and ULTIBRO[®] BREEZHALER[®] capsules in a dry place.
- Avoid getting the drug powder in your eyes.

Additional information

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. The chances of the capsule shattering will be increased if the capsule is pierced more than once (step 7).

How to clean your inhaler

Never wash your inhaler with water. If you want to clean your inhaler wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry.

Overdose:

If you think you have inhaled too much ULTIBRO[®] BREEZHALER[®], contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you accidentally take a larger dose of ULTIBRO[®] BREEZHALER[®] you may feel shaky, have a headache, or feel like your heart is beating faster than usual. Talk to your doctor or pharmacist right away if this occurs.

Missed Dose:

If you forget to inhale a dose, inhale a dose as soon as possible on the same day. However, do not inhale two doses on the same day. Then inhale the next dose as usual.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients using ULTIBRO[®] BREEZHALER[®] may experience side effects, although not everybody gets them.

Side effects may include:

- Feeling of pressure or pain in the cheeks and forehead (possible symptoms of sinusitis)
- Runny or stuffy nose, sneezing
- Dizziness
- Headache
- Cough
- Sore throat/or mouth
- Upset stomach, indigestion
- Cavities
- Pain in muscles, bones or joints
- Pain in extremities (e.g. arms or legs)
- Fever

- Chest pain
- Problem falling asleep
- Tingling or numbness
- Nose bleeds
- Dry mouth
- Skin itching/rash
- Muscle spasm
- Tiredness
- Nausea, vomiting, diarrhea and abdominal pain (possible symptoms of gastroenteritis)
- Combination of sore throat, runny nose (signs of nasopharyngitis)
- Fast heart beat
- Irregular heart beat (palpitations)
- Swollen hands, ankles and feet
- Muscle pain, aches or tenderness
- Blocked nose, sneezing, coughing, headache with or without fever (signs of upper respiratory tract infection)
- Disorders of the voice - hoarse, weak, breathy or strained voice, with or without pain or discomfort in the throat

If any of these affects you severely, **tell your doctor, nurse or pharmacist.**

ULTIBRO® BREEZHALER® can cause abnormal blood test results such as decreased levels of potassium and increased blood sugar. Your doctor will decide when to perform blood tests and will interpret the results.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Paradoxical Bronchospasm: Sudden worsening of shortness of breath and wheezing right after inhaling ULTIBRO® BREEZHALER®			✓
Glaucoma: New or worsened pressure in your eyes, eye pain or discomfort, temporary blurred vision, seeing halos of bright colours around lights, red eyes			✓
Common			✓
Serious Allergic Reaction: difficulties in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching, and hives			✓
Increased blood sugar: Increased thirst, frequent urination, increased appetite with weight loss, tiredness		✓	
Urinary retention: Difficulty and pain when passing urine, needing to go often, urination in a weak stream or drips		✓	
Bladder Infection: painful and frequent urination		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Uncommon Crushing chest pain with increased sweating (signs of insufficient blood and oxygen supply of the heart). This may be a serious heart problem.			✓
Irregular heartbeat	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Not known	Decreased levels of potassium in the blood: Irregular heartbeats, muscle weakness and spasms and generally feeling unwell		✓	
	Angioedema: Swelling mainly of the tongue, lips, face and throat		✓	

This is not a complete list of side effects. For any unexpected effects while taking ULTIBRO® BREEZHALER®, contact your doctor, nurse or pharmacist immediately.

HOW TO STORE IT

Do not use after the expiry date shown on the box.

Store ULTIBRO® BREEZHALER® at room temperature between 15 to 25°C.

Store the capsules in the original package, in a dry place in order to protect from heat and moisture. Do not remove capsules from blister pack until immediately before use.

Keep this medicine out of the reach and sight of children

Each inhaler should be disposed of after 30 days of use.

Do not use this medicine if you notice that the pack is damaged or show signs of tampering. Ask your pharmacist how to dispose of medicines you no longer use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the product monograph, prepared for health professionals can be found at: www.novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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Last revised: December 13, 2016

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