

DRAFT

Begin Reporting Here

1. Login

Email

Password

[Forgot your password?](#)

Remember me

Login

2. Report As Guest

Not ready to create an account but would like to submit a report?

Or

You can do that here.

Report as Guest

Account Benefits

- Save a draft
- Easy follow up
- View submissions
- Fast data entry

Create

Account Registration

DRAFT

*=Required

***Which of the following best describes you?**

- A food Facility or responsible party that manufactures, processes, packs, or holds food who is submitting a reportable food report
- A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food
- A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving pet food
- A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving pet food
- A marketing authorization holder (manufacturer) for an animal drug who is submitting a product problem and/or an adverse event report
- A Clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study
- A healthcare professional submitting a product problem and/or health-related problem report involving a tobacco product
- A consumer or concerned citizen who is submitting a product problem and/or health-related problem report involving a tobacco product
- None of the above describes me

Your Contact Information

*First Name

*Last Name

*Country

*Phone

*Street Address Line 1

Street Address Line 2

*City/Town

*State

*State/Province

*ZIP/Postal Code

<Next 4 prompts shown only if user answers Healthcare Professional for the question "Which of the following best describes you?">

Organization

Title

Healthcare professional type

Describe Other

Your Login Credentials

*Email Address (this will be your login ID)

*Confirm Email Address

Select a password:

- at least 8 characters long
- at least one symbol/special character (Example: !, @, #, %, ^, &, *, _, -, .)

*Password

*Confirm Password

*Security Question

*Security Question Answer

Submit **Exit**

<Submit: Save Changes; Create user account and send email to user to validate user email and allow account access/login>

My Report History

My Account

My Account

* = Required

Personal Information- Drug Manufacturer

Change Password and Security Question

* Reporter Role

Representative of a manufacturer for an animal drug (FdaGL42) ▼

Read only

* First Name

* Last Name

Job Title

* Email Address (this will be your Login ID)

* Confirm Email Address

* Primary Phone

Other Phone

Fax

Address Information - Drug Manufacturer

Organization Name

* Country

United States ▼

* Street Address 1

Street Address 2

* City/Town

State

1) State/Province

* Zip/Postal Code

1) ?

Save

Exit

1) Show if country <> US

1) If a ZIP/Postal Code is not applicable to your address, please type "NA" in the field.

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New Guest Report

DRAFT

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at another time, please return to the home and create an account.

* **Select the option that best describes what you want to do:**

- Start a new report
- Follow-up on a report previously submitted as guest
- Follow-up on a report previously submitted as a logged in user.
- None of the above

* **Which of the following best describes you?**

- A food Facility or responsible party that manufactures, processes, packs, or holds food who is submitting a reportable food report
- A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food
- A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving pet food
- A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving pet food
- A marketing authorization holder (manufacturer) for an animal drug who is submitting a product problem and/or an adverse event report
- A Clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study
- A healthcare professional submitting a product problem and/or health-related problem involving a tobacco product
- A consumer or concerned citizen who is submitting a product problem and/or health-related problem involving a tobacco product
- None of the above describes me

[Begin](#)[Exit](#)

My Report History

My Account

My Reports**Draft Reports** [Click column header to sort the column](#)

Date Saved (EST)	Report ID	Title	Type
<input checked="" type="radio"/> 01/17/2012 05:39:41 PM	FPSR137 (I)	Test CTP Initial	Voluntary Tobacco Product Report
<input type="radio"/> 12/19/2011 08:45:33 AM	FPSR100 (F)	Cigar Leaves	Voluntary Tobacco Product Report

[Start New Report](#)[Edit](#)[Delete](#)

|< < Page 1 of 1 > >|

[<Start New Report: Go to the CTP Report Introduction Page>](#)[<Edit: Load the selected Draft report and allow user to Edit the Draft report>](#)[<Delete: Allow user to Delete selected Draft report>](#)**Submitted Reports Available for Follow-Up** [Click column header to sort the column](#)

Date Submitted (EST)	Report ID	ICSR#	Title	Type
<input checked="" type="radio"/> 01/17/2012 05:39:41 PM	FPSR111 (I)	FPSR111 (I)	Test CTP Initial	Voluntary Tobacco Product
<input type="radio"/> 12/25/2011 09:45:33 AM	FPSR118 (F)	FPSR118 (F)	Snuff Product Package	Voluntary Tobacco Product

[Start Follow-Up Report](#)[View](#)[View PDF](#)

|< < Page 1 of 1 > >|

[<Start Follow-Up Report: Load the selected report and start follow-up from the CTP Report](#)[<View: Load the selected report and in View mode starting from the CTP Report](#)[<View PDF: Load the selected report's PDF and display the submitted PDF>](#)**DRAFT**[Exit](#)

DRAFT

Introduction

*=Required


Tobacco Product Reports are for healthcare professionals and consumers to report on FDA-regulated and non-regulated tobacco products for consumption in the U.S.

Please be advised that under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement or representation to the U.S. Government is subject to criminal penalties.

This report has up to six sections. After you answer the questions on this page, you may complete the other pages in any order. The amount of time required to complete this report will vary depending upon the information you have to provide. As you complete each field, your responses are automatically saved. To submit this report, you must complete all required fields that are marked with a red asterisk.

Please note: This report is not considered an admission that a product caused or contributed to serious injury, illness or death. This report shall be considered under section 756 of the Food, Drug, and Cosmetic Act [21 U.S.C. 379v](#) and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness. You may upload such a statement as an attachment to this report, if desired.

*Create a name to help you find this report in the future (max length 50 characters)

*What type of report are you submitting? 

If a person experienced a health problem from use of a tobacco product, select Adverse Event (health problem). If the product had a bad smell, bad taste, foreign material in it, or some other problem, select Product Problem. If there was a health problem and a product problem, select Both.

Adverse Event (health problem)

Product Problem

Both

Original Source Individual Case Safety Report Number

<System generated, read only; show only if report = follow-up>

Original Submission Date

<System Generated; Read Only; show only if report = follow-up>

Responding to a FDA request?

Yes No

<Show only if the Report is a Follow-up>

Follow-up Reason

Please Select [<Show only if the Report is a Follow-up>](#)

Save Draft

Exit

Submit

Back

Next

<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

- Introduction
- Contact Information
- Problem Summary
- Tobacco Product
- Other Products Used
- Attachments
- My Report History

Contact Information

*=Required

Please note: Your contact information will be used only by the FDA in reference to this report, and in accordance with the Department of Health and Human Services privacy policy. There is a link to this policy on the bottom of this page for your reference.

Your Contact Information

Check here if you wish to remain anonymous <If Checked, hide all Prompts through ZIP/Postal Code; only asked if guest reporter>

First Name <If registered user, First Name, Last Name, Email, Confirm email, Country, Phone. Street Address 1, Street Address 2, City/Town, State, Zip are prefilled from the registration information.>

Last Name

May the FDA contact you to follow-up if necessary? Yes No <If Yes, next prompt is shown>

Preferred method of contact

Email <If selected, Email information is required>

Phone <If selected, Phone information is required>

Address <If selected, Address information is required>

Email

Confirm Email

Country <If USA, Phone uses US format and State is drop down list>

Phone

Street Address Line 1

Street Address Line 2

City/Town

State <If Country=USA, State is drop down list>

State/Province

ZIP/Postal Code

Sender Category

Organization

Title

Are you the person who experienced health problems associated with a tobacco product? Yes No <Hidden if Product Problem>

Please describe your relationship to the person who experienced the health problem

Healthcare professional type

Describe other

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<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

DRAFT

- Introduction
- Contact Information
- Problem Summary
- Tobacco Product
- Other Products Used
- Attachments
- My Report History

Problem Summary

*=Required

Affected Person

Gender Male Female

Pregnant Yes No Unknown [<Show only if Gender is female>](#)

Race (select one or more)
 American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White

Ethnicity
 Hispanic or Latino
 Not Hispanic or Latino

Birth date of the person who experienced the health problem / / [<Partial date allowed>](#)

Age of the person when the health problem occurred Select Unit of Measure

The Birth Date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

Please list any known pre-existing health problems for the affected person

Problem Description

Product Problem Type Appearance, look, smell, or taste is wrong or not as expected
 Child safety issue
 Damaged, broken or defective product, accessory, or packaging
 Foreign material (something is present that does not belong in the product)
 Incorrect use - accidental (product was used incorrectly by accident)
 Incorrect use - intentional (product use was used incorrectly on purpose)
 Labeling or instructions for the use are incorrect, misleading or difficult to understand
 Number of items in package is wrong
 Other product problem not listed
 Product functions in a way that is unexpected or incorrect or product is difficult to use
 Product mixup (product was mistaken for another product or accidentally substitute for another product)
 Wrong product in package

<Shown only if Report Type = Product Problem or Both>

This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

Please provide the health problem/product problem start and end dates, or how long the health problem lasted

Health Problem/Product Problem Start Date / / [<Partial dates will be accepted MM/YYYY and YYYY; Start Date cannot be after today's date>](#)

Health Problem/Product Problem End Date / / [<Partial dates will be accepted MM/YYYY and YYYY; End date cannot be before the start date>](#)

How long did the health problem event last? Select Unit of Measure

This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

* What are the main symptoms or health problems (select up to 5)

<input type="checkbox"/> Abnormal heart rhythm	<input type="checkbox"/> Achy joints
<input type="checkbox"/> Addiction to nicotine/tobacco product	<input type="checkbox"/> Allergic reaction
<input type="checkbox"/> Anxiety	<input type="checkbox"/> Aortic aneurysm
... <Insert full list of values as provided in the data requirements>...	... <Insert full list of values as provided in the data requirements>...
<input type="checkbox"/> Upper respiratory infection/cold	<input type="checkbox"/> Urinary tract infection
<input type="checkbox"/> Use with another product led to a problem	<input type="checkbox"/> Visual change (impaired vision)
<input type="checkbox"/> Vomiting	<input type="checkbox"/> Wheezing

* Please Describe the Health Problem or Product Problem:

Do any of these apply to the health problem? (Select one or more)

<input type="checkbox"/> Death
<input type="checkbox"/> Disability
<input type="checkbox"/> Life Threatening
<input type="checkbox"/> Birth Defect
<input type="checkbox"/> Hospitalization
<input type="checkbox"/> Treatment Received
<input type="checkbox"/> Multiple Deaths and Serious Injuries
<input type="checkbox"/> Pediatric Death
<input type="checkbox"/> None of the Above

<If none of the above is selected along with another checkbox, give user the message: Please check your answer. If "None of the above" is selected, all other boxes must be blank>

Outcome to date Please Select

<Hidden if outcome = death>

Was the person taken to an emergency facility? Yes No Unknown

Was the person evaluated by a healthcare professional? Yes No Unknown

Date the person was first seen by a healthcare professional for this health problem / / [<Partial date allowed>](#)

This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

Has this person ever had a similar health problem or product problem? Yes No

Please describe the similar health problem or product problem

Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work)

Date of Death / / [<Partial date allowed>](#)

This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

Reported Cause of Death

<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

Tobacco Product

* = Required

Please enter information about the tobacco product that may have caused the health problem/product problem

Tobacco Product Details

* Product Type

Description of Other Tobacco Product Type

Product Subtype

Description of Other Tobacco Product Subtype

Changing the product type may cause selected component types to be deleted.

Breed Name or Product Name

When did the person purchase this product? Partial date allowed. If mmyyyy, must be <= today's mmyyyy. If mmdyyyy, must be <= today's date.

<Tool tip will display sample of UPC code> Universal Product Code (UPC) from Label

Did the product come from another country?

Does the person still have the product? Yes No Unknown

Do you know where the product was purchased? Yes No If yes, display Product Purchase Location Group

Product Purchase Location

How was this product purchased?

<If user selects Web mail order, only show Purchase Location Name and Website Address> <If user selects Phone mail order, only show Purchase Location Name and Phone> <If user selects In a Store, hide Website Address>

Purchase Location Name

Country

Phone

Street Address Line 1

Street Address Line 2

City/Town

State

State/Province

ZIP/Postal Code

Web Address

Do you know who manufactured this product? Yes No If Yes, display the Product Manufacturer Information group of prompts

Product Manufacturer Information

Firm/Organization Name

Country

Phone

Street Address Line 1

Street Address Line 2

City/Town

State

State/Province

ZIP/Postal Code

Web Address

Product Use Details

****Please see addendum wireframe 75 Product Usage for all possible display labels for product usages, based on product type selected****

On average, number of smoking sessions Select Unit of Measure

How long has the person been using this brand? Select Unit of Measure

When did the person open the package and start using the product that may have caused the health problem? Partial date allowed. Must be <= today's date.

When did the person stop using the product that may have caused the health problem? Partial date allowed. Must be >= Start date.

Was the product being used when the health problem occurred? Yes No Unknown

Did the person use this product before without a problem? Yes No Unknown

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)? Yes No Unknown

Please explain how the product was changed prior to its use

Reaction and Product Relatedness

How soon after the product was last used did the health problem occur? Select Unit of Measure

Did the person stop using the product when he/she had the health problem?

Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used? Show if answer to "Did the person stop using the product when they experienced the adverse event?" = yes

Did the person start using the product again? Show if answer to "Did the person stop using the product?" = yes

How long was it before the person started using the product again? Select units of Measure Show if answer to "Did the person start using the product again?" = yes

Did the health problem happen again after the person started using the product again? Show if "Did the person start using the product again?" = yes

In your opinion, how likely is it that the use of the product is related to the health problem? Show if answer to "Did the adverse event happen again after the person started using the product again?" = yes Show if reporter is a healthcare professional

Some tobacco products have components that may be purchased in different locations or from different manufacturers. For example, for roll-your-own cigarettes, the cigarette papers and the tobacco may have different purchase locations and manufacturers. You can report the purchase locations and manufacturers for components in the component section below.

Product Components

<Product Components section and all data within this section shown only when selected Product Type has associated Components>

<Component Type prefilled in the Grid based in user selection of Product Type>

Component Name	Component Type	Purchase Location	Manufacturer
<input checked="" type="radio"/> Joe's Tobacco	Tobacco	The Tobacco Shop	John's Tobacco Co.
<input type="radio"/> My Wrapper	Blunts	Same	Joe's Cigars Inc.

|< < Page 1 of 1 > >|

Add: Open the lightbox and allow user to enter component information
 Edit: Open the lightbox and allow user to Edit selected component information
 Delete: Allow user to Delete selected component information

<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

- Cigarettes
- Roll-your-own cigarettes
- Moist snuff
- Dry snuff (lip or cheek)
- Chewing tobacco
- Iq'mik
- Disolvable
- Lotion/Gel
- Chimo
- Guahaku
- Gul
- Gutkha/Paan with tobacco/Paan masala
- Khaini
- Maras
- Mawa
- Mshri
- Nass/Naswar/Niswar
- Khawm/Qiwam
- Red tooth powder
- Toombak
- Tubar
- Zarda
- Other
- NA

Values:
 Website Mail Order
 Phone Mail Order
 In a Store

per day
 per week
 per month

Values:
 less than 7 days
 Weeks
 Months

This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. If your date provides only year information, please use the YYYY format.

Minutes
 Hours
 Days
 Weeks
 Months

Yes
 No
 Unknown

Yes
 No
 Unknown
 Not Applicable

Seconds
 Minutes
 Hours
 Days
 Months
 Weeks
 Years

Related
 Probably Related
 Possibly Related
 Unlikely Related

DRAFT

Unknown

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Other Products Used

*=Required

Is the affected person currently using other tobacco products (within past month)? Yes No Unknown <If yes, show Other Tobacco Products Currently Used group>

Select Add button below if the person uses other tobacco products

Other Tobacco Products Currently Used

Brand Name/Product Name

Cigarettes
 Cigars

Add **Edit** **Dele** <Add: Open the lightbox and allow user to enter Other Product Used information> |< < Page 1 of 1 > >|
<Edit: Open the lightbox and allow user to Edit selected Product information>
<Delete: Allow user to Delete selected Product information>

Has the affected person used other tobacco products on a regular basis in the past? Yes No Unknown <If yes, show Other Tobacco Products Used in the Past group>

Other Tobacco Products Used in the Past

Select Add button below if the person used other tobacco products in the past

Brand Name/Product Name

Chewing Tobacco
 Snus

Add **Edit** **Dele** <Add: Open the lightbox and allow user to enter Other Product Used information> |< < Page 1 of 1 > >|
<Edit: Open the lightbox and allow user to Edit selected Product information>
<Delete: Allow user to Delete selected Product information>

Does the person who had the adverse event also drink alcohol? Yes No

How many drinks per week? Please Select <Show only if "Does the person who had the adverse event also drink alcohol?" = Yes>

<5 drinks/week
5-6 drinks/week
7+ drinks/week

Please describe anything else you think the FDA should know about this health problem

[Text Area]

ABC

Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

[Text Area]

Save Draft **Exit** **Submit** **Back** **Next**

<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

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Other Tobacco Products Currently Used Details

Brand Name or Product Name

Product Type

Please Select ▼

Description of Other Tobacco Product Type

<Show only if Other is selected for Product Type>

Product Subtype

Please Select <Show only if selected Product Type has associated Product Subtype> ▼

Description of Other Tobacco Product Subtype

<Show only if Other is selected for Other Product Subtype>

****Please see addendum wireframe 75 Product Usage for all possible display labels for product usages, based on product type selected****

On average, number of smoking sessions

 ▼

per day
per week
per month

Duration of Use

Please Select ▼

Less than 1 month
1-6 months
6-12 months
More than 12 months

Save

Cancel

DRAFT

Other Tobacco Product Used in the Past

Brand Name or Product Name

Product Type

Please Select ▼

Description of Other Tobacco Product Type

<Show only if Other is selected for Product Type>

Product Subtype

Please Select <Show only if selected Product Type has associated Product Subtype> ▼

Description of Other Tobacco Product Subtype

<Show only if Other is selected for Other Product Subtype>

****Please see addendum wireframe 75 Product Usage for all possible display labels for product usages, based on product type selected****

On average, number of smoking sessions

 Select Unit of Measure ▼

Duration of Use

Please Select ▼

per day
per week
per month

Less than 1 month
1-6 months
6-12 months
More than 12 months

Save

Cancel

Name: Voluntary Tobacco
Product Report
FPSR257 (1)
Created: 01/21/2012

Welcome Reporter Jane

HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

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Attachments

*=Required

You may upload up to 5 (10 MB each) attachments per submission. The following file extensions are permitted:
.doc,.docx,.pdf,.bmp,.gif,.jpg,.jpeg,.png,.tif,.tiff,.txt,.rtf,.xls,.xlsx,.wpd.

Upload Attachments

Product Name	Type	Description
<input checked="" type="radio"/> New Text Document.txt	Certificate	County Paper Scan
<input type="radio"/> History and Background.doc	Medical History	Medical Information

Add

Edit

Delete

<Add: Open the lightbox and allow user to upload attachments>

|< < Page 1 of 1 > >|

<Edit: Open the lightbox and allow user to Edit selected uploaded attachment information>

<Delete: Allow user to Delete selected uploaded attachment information>

Save Draft

Exit

Submit

Back

Next

<Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>

<File Attachment Lightbox: Display Only to Add, Edit or Delete Attachment Information>

Attach File

*File to attach

Brows

*Description of Attachment

*Type of Attachment

Please Select

DRAFT

Save

Cancel

Name: Voluntary Tobacco
Product Report
FPSR257 (I)
Created: 01/21/2012

Welcome Reporter Jane

[HOME](#)

[FAQS](#)

[RELATED LINKS](#)

[CONTACT US](#)

[FEEDBACK](#)

[HELP](#)

[LOGOUT](#)

[My Report History](#)

Report Submission Confirmation

Congratulations! Your initial Voluntary Tobacco Product Report, ID FPSR257, was successfully submitted on 01/21/2012 2:07:02 PM EST to FDA, and it was issued an Individual Safety Report (ICSR) Number of FPSR257.

Thank you for using the Safety Reporting Portal.

[View Report](#)

[View Report](#)

[Return to My Report](#)

<View Report: Allow user to view the submitted report>

<View Report PDF: Allow user to view the submitted report in PDF format>

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Product Usage

If product type = cigarette, roll-your own, cigar, small cigar, bidis, kreteks (clove cigarettes)

On average, number smoked

Please select ▼

Values:
per day
per week
per month
per year

If product type = Pipe tobacco

On average, number of pipes of tobacco smoked

Please select ▼

If product type = Hookah, vaporizer

On average, number of smoking sessions

Please select ▼

If product type = e-cigarette

On average, number of cartridges used

Please select ▼

If product type = chewing tobacco

On average, number of plugs, chaws, or wads used

Please select ▼

If product type =

On average, number of single use pouches, pinches, dips, or rubs used

Please select ▼

Values:
per day
per week
per month
per year

If product type = snus

On average, number of single use pouches or rubs used

Please select ▼

If product type = gudhaku, maras, mawa, mishri, nass/naswa/niswar, khiwam/qiwam, red tooth powder, toombak, tuibar, zarda, snus, lotion/gel, or other

On average, number of pieces used

Please select ▼

If product type = gudhaku, maras, mawa, mishri, nass/naswa/niswar, khiwam/qiwam, red tooth powder, toombak, tuibar, zarda, snus, lotion/gel, or other

On average, number of pinches used

Please select ▼

Values:
per day
per week
per month
per year

If product type = Gul

On average, number of dabs used

Please select ▼

DRAFT