Please read Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers available at www.JanssenCOVID19vaccine.com/EUA-Recipient-factsheet and discuss any questions you have with the vaccination provider.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.
The Janssen COVID-19 Vaccine vaccination schedule is a single dose.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported include:

- Injection site reactions: pain, redness of the skin, and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. This vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form. In addition, you can report side effects to Janssen Biotech Inc. at 1-800-565-4008.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Currently, there is no FDA approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Feb/27/2021

cp-205985v1

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 02/2021

Notice of Privacy Practices

Original notice effective April 14, 2003
Revised notice effective September 23, 2013

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

PLEASE READ CAREFULLY.

WE ARE REQUIRED BY LAW TO PROTECT MEDICAL INFORMATION ABOUT YOU.

We are required by law to protect the privacy of medical information about you and that identifies you. We are also required to give you this Notice about our Privacy Practices, explaining our legal duties and your rights concerning your health information. We must follow the privacy practices described in this Notice while it is in effect. We reserve the right to make changes to our privacy practices and the terms of this Notice at any time, provided such changes are permitted by applicable law. We reserve the right to make changes in our privacy practices and the terms of our Notice effective for all health information that we maintain, including health information we created or received before we made the changes. Before we make a significant change in our privacy practices, we will change this Notice and make the new Notice available upon request. You may request a copy of our Notice at any time. If you have questions about information in this Notice or about our privacy policies, procedures or practices, you can contact us using the contact information at the end of this notice.

HOW WE MAY USE AND DISCLOSE MEDICAL INFORMATION ABOUT YOU IN CERTAIN CIRCUMSTANCES

We use and disclose health information about you for treatment, payment, and healthcare operations. The examples given are for illustrative purposes and are not exhaustive.

- **Treatment:** We may use or disclose your health information to a physician or other healthcare provider providing treatment to you. For example, your health information may be provided to another health care practitioner to whom you have been referred to ensure that the party has the necessary information to diagnose or treat you.
- **Payment:** We may use and disclose your health information to obtain payment for services we provide to you. For example, we may disclose your health information to your health plan in order to obtain approval for a procedure.
- **Healthcare Operations:** We may use and disclose your health information in connection with our healthcare operations. For example, we may disclose your health information for case management purposes. Healthcare operations may include quality assessment and improvement activities, reviewing the competence or qualifications of healthcare professionals, evaluating practitioner and provider performance, conducting training programs, accreditation, certification, licensing or credentialing activities.
- **Your Authorization:** Unless you give us a written authorization, we cannot use or disclose your health information for any reason except those described in this Notice. In addition to our use of your health information for treatment, payment or healthcare operations, you may give us written authorization to use your health information or to disclose it to anyone for any purpose. If you give us an authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosures permitted by your authorization while it was in effect.
- **Psychotherapy Notes:** Most uses and disclosures of psychotherapy notes will require your written authorization. You may inquire about specific uses and disclosures of psychotherapy notes permitted without your authorization.
- **Fundraising:** You have the right to opt out of receiving fundraising communications.
- **Genetic Information:** Your genetic information will not be used or disclosed for underwriting purposes.
- **Sale of Health Information:** Any use or disclosure that constitutes the sale of health information is not permitted without your authorization.
- **Disclosures to You, To Your Family, or to Your Friends:** We must disclose your health information to you in accordance with the Patient Rights section of this Notice. We may disclose your health information to a family member, friend or other person to the extent necessary to help with your healthcare or payment for your healthcare, but only if you authorize us to do so.
- **Persons Involved In Your Care:** We may use or disclose health information to notify, or assist others in notifying a family member, your personal representative or other person responsible for your care of your location, your general condition, or death. If you are present, we will provide you with an opportunity to object to such disclosures of your health information prior to use or disclosure of that information. In the event you become incapacitated or have a medical emergency, we will disclose your health information based on our professional judgment that such disclosure is directly relevant to that person's involvement in your healthcare. We will also use our professional judgment and experience to make decisions about your best interest in allowing a person to pick up filled prescriptions, medical supplies, x-rays, or other similar forms of health information.

- **Marketing Health-Related Services:** Use or disclosure of health information for marketing purposes will require your written authorization.
- **Required by Law:** We may use or disclose your health information when we are required to do so by law.
- **Abuse or Neglect:** We may disclose your health information to appropriate authorities if we reasonably believe that you may be the victim of abuse, neglect, domestic violence or other crimes. We may disclose your health information to the extent necessary to avert a serious threat to your health or safety or the health or safety of others.
- **National Security:** We may disclose to military authorities the health information of Armed Forces personnel under certain circumstances. We may disclose to authorized federal officials health information required for lawful intelligence, counterintelligence, and other national security activities. We may disclose to correctional institutions or law enforcement officials having lawful custody of protected health information of inmate or patient under certain circumstances.
- **Appointment Reminders:** We may use or disclose your health information to provide you with appointment reminders (such as voicemail messages, postcards, or letters).

PATIENT RIGHTS

- **Access:** You have the right to look at or get copies of your health information, with limited exceptions. You may request that we provide copies in a format other than photocopies. We will use the format you request unless we cannot practicably do so. You must make this request in writing to obtain access to your health information. You may obtain a form to request access from your care provider. We may charge you a reasonable cost-based fee for expenses such as copies and staff time. For details about when this request may be denied, please speak with your care provider.
- **Disclosure Accounting:** You have the right to receive a list of instances in which we or our business associates disclosed your health information for purposes other than treatment, payment, healthcare operations and certain other activities for the last 6 years, but not before April 14, 2003. If you request this accounting more than once in a 12-month period, we may charge you a reasonable, cost-based fee for responding to the additional requests.
- **Restriction:** You have the right to request that we place additional restrictions on our use or disclosure of your health information. Except in the case of paying out of pocket as described below, we are not required to agree to these additional restrictions, but if we do, we will abide by our agreement (except in an emergency).
- **Paying Out of Pocket:** If you are paying out of pocket **in full** for a service or item in question, then you have the right to request that we restrict disclosure of your health information related to that service or item for purposes of payment or health care operations. Paying only the insurance deductibles or copayments does not exercise this right. We must abide by this request unless disclosure is otherwise required by law. You must request additional restrictions and pay out of pocket in full to restrict to restrict disclosure of follow up care.
- **Alternative Communication:** You have the right to request that we communicate with you about your health information by alternative means or to alternative locations. **{You must make your request in writing.}** Your request must specify the alternative means or location, and provide satisfactory explanation how payments will be handled under the alternative means or location you request.
- **Amendment:** You have the right to request that we amend your health information. (Your request must be in writing, and it must explain why the information should be amended.) We may deny your request under certain circumstances.
- **Electronic Notice:** If you receive this Notice on our website or by electronic mail (e- mail), you are entitled to receive this Notice in written form upon request.
- **Breach Notification:** You have the right to be notified if we determine that a breach of your health information has occurred.

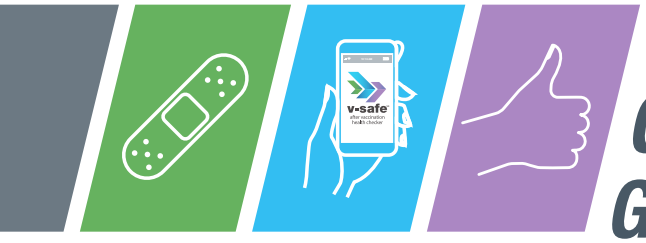
QUESTIONS AND COMPLAINTS

If you want more information about our privacy practices or have questions or concerns, you may contact us using the information at the end of this notice. If you are concerned that we may have violated your privacy rights, or if you disagree with a decision we made about access to your health information or in response to a request you made to amend or restrict the use or disclosure of your health information or to have us communicate with you by alternative means or at alternative locations, you may complain to us using the contact information listed at the end of this Notice. You also may submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address to file your complaint with the U.S. Department of Health and Human Services upon request.

We support your right to the privacy of your health information. We will not retaliate in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.

Transylvania County Government
101 South Broad Street, Brevard, NC 28712
www.transylvaniacounty.org

Transylvania Public Health
106 East Morgan Street, Suite 105, Brevard, NC 28712
828.884.3135 | www.transylvaniahealth.org



Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2 p.m. local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the ***v-safe*** website using one of the two options below:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, ***v-safe*** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.
   You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

TRANSYLVANIA PUBLIC HEALTH

106 EAST MORGAN STREET
SUITE 105
BREVARD, NC 28712
828.884.3135
transylvaniahealth.org

EVERYDAY. EVERYWHERE. EVERYONE.